IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Volume 4
Pages 661 through 845

Defendant.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

TUESDAY, OCTOBER 9, 2018, 9:00 A.M.

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For the Plaintiffs: CHILDERS, SCHLUETER & SMITH
1932 North Druid Hills Road, Ste 100
Atlanta, Georgia 30319
BY: C. ANDREW CHILDERS

URY & MOSKOW
883 Black Rock Turnpike
Fairfield, Connecticut 06825
BY: NEAL L. MOSKOW

(Appearances continued next page...)

Reported by: KATHY L. SWINHART, CSR
LISA A. COOK, RPR-RMR-CRR-FCRR
Official Court Reporters
(304) 528-2244

Proceedings reported by mechanical stenography, transcript produced by computer-aided transcription.

APPEARANCES (Continued)

For the Plaintiffs:

FERRER, POIROT & WANSBROUGH
2100 RiverEdge Parkway, Suite 1025
Atlanta, Georgia 30328
BY: RUSSELL ABNEY
and HUNTER VANCE LINVILLE

For the Defendant:

TUCKER ELLIS
925 Euclid Avenue, Suite 1150
Cleveland, Ohio 44115
BY: JOHN Q. LEWIS

COVINGTON & BURLING
One City Center
850 Tenth Street NW
Washington, D.C. 20001
BY: PHYLLIS ALENE JONES
and NICHOLAS HAILEY
and JESSICA PEREZ

JACKSON KELLY
Post Office Box 553
Charleston, West Virginia 25322
BY: GRETCHEN M. CALLAS

Also Present:

CLAUDE R. KNIGHT, Plaintiff

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HUNTINGTON, WEST VIRGINIA

TUESDAY, OCTOBER 9, 2018, 9:06 A.M.

THE COURT: Good morning.

Before we bring the jury in, I note that the defense filed a motion with respect to Dr. Ashhab's opinions. When do you expect to call him as a witness?

MR. CHILDERS: Right after lunch, Your Honor.

THE COURT: All right. Have you seen the motion?

MR. CHILDERS: I have.

THE COURT: Will you be prepared to at least argue it a little bit later this morning?

MR. CHILDERS: Then or now, whatever you prefer.

THE COURT: Well --

MR. CHILDERS: At any point today we can argue it.

THE COURT: All right. I'd rather bring the jury out. All right. Are we ready for the jury?

MR. CHILDERS: Yes, Your Honor.

(Jury returned into the courtroom at 9:08 a.m.)

THE COURT: Good morning. Welcome back. We're ready to have the plaintiff call their next witness.

MR. CHILDERS: Thank you, Your Honor.

Ladies and gentlemen, this is going to be another video. Plaintiffs are going to play the video of Dr. Dawn MacFarland. It's about an 18-minute video. And then the defendants will play their examination.

**VIDEOTAPED DEPOSITION OF DAWN MACFARLAND, PLAINTIFFS' WITNESS, PLAYED.**

(Videotaped deposition paused.)

MS. JONES: Your Honor, you had asked us to give folks a stretch break during some of the videos. We have a little bit left but we thought this might be an appropriate time.

THE COURT: All right. Take a minute. If you'd like to stretch, use the restroom, get a drink, feel free to.

(Pause in proceedings from 10:20 a.m. until 10:29 a.m.)

(Jury not present)

THE COURT: All right. So since the jury obviously wanted to take a little more than just a minute or two break and none of them are present in the courtroom, I'd like to take up the defense motion at least to hear the plaintiffs' response.

Are you ready to do that, Mr. Childers?

MR. CHILDERS: Yes, Your Honor.

THE COURT: Go ahead.

MR. CHILDERS: We did read this last night when it came in. I'm not going to comment on the timing of it, but I would just say that we don't intend to elicit opinions from Dr. Ashhab relating to these two issues. But these are facts that things are or are not in the label. And I do

expect him to testify, yes, they are, or, no, they're not in the label, but he's not going to offer an opinion as to whether or not it should have been in the label.

MR. LEWIS: I guess, Your Honor, that's what, that's what the concern is. Dr. Ashhab did not mention either in his report or in his deposition that there's any criticism of the label whatsoever for those purposes. I don't think that he ought to be able to just float in the suggestion or imply to the jury that there's a deficiency because of that.

THE COURT: How would those facts be relevant to his opinions if they weren't facts he relied upon in reaching his opinion?

MR. CHILDERS: Well, he relied on the entirety of the label, both -- all of the labels. And we disclosed that, that he looked at all of them.

THE COURT: And that's fine. He can testify --

MR. CHILDERS: Right.

THE COURT: -- that the label doesn't say that this was tested on severe, severely compromised renal patients or that the 75-milligram dose was tested.

MR. CHILDERS: Correct.

THE COURT: So I think he can do that.

MR. LEWIS: Okay. I guess, Your Honor, I just, if I may, I think it's very misleading to the jury based on the

way that they've presented the case thus far for Dr. Ashhab to mention those facts in the same context where he's criticizing the label in a general way, particularly when it was never -- and they could have disclosed this to us. That could have been a criticism of Dr. Ashhab. He could have mentioned that fact during his deposition or in his report. It's nowhere to be found in anything that he said to date.

And it will be very misleading to this jury to, to shoehorn in those facts into a general criticism of our label. I don't think it's relevant to his opinion. They're not facts that he relied upon or ever mentioned. And I don't think he should be permitted to even mention it.

MR. CHILDERS: Facts are facts, Judge. I'm not really sure how he can talk about the label and not, and not be allowed to talk about particular parts.

Again, I'm not going to elicit any opinion from him it should have been in there, it shouldn't have been in there. This is the information that Dr. MacFarland had when she made the decision to prescribe it. This is the information that the patients -- well, actually, he's not even going to talk about the Medication Guide on that issue. It just -- that's the information she had when she made the decision. That's, that's the limit of where we're going to go with that.

THE COURT: Well, I want to think about it. I may

have some more inquiry before we get to it. When do you expect to get to him?

MR. CHILDERS: We're going to play Dr. Abdelgaber's deposition after this. And then he would be the next witness I assume right after we take our lunch break, Your Honor.

THE COURT: How long is Dr. Abdelgaber's deposition?

MR. CHILDERS: Our portion, Your Honor, is 47 minutes and the defense is 30 minutes.

THE COURT: Okay, all right. Well, I want to think about it. We may have some more argument when we take the break.

MR. CHILDERS: Yes, sir.

THE COURT: Let's see if the jury is ready.

(Jury returned into the courtroom at 10:33 a.m.)

THE COURT: All right. We're ready to resume.

(Videotaped deposition resumed.)

(Videotaped deposition paused.)

MS. JONES: That's the conclusion of the defense examination.

THE COURT: All right.

MR. CHILDERS: We have an extremely short redirect. Don't blink. It's only 25 seconds long.

THE COURT: Go ahead.

(Videotaped deposition resumed.)

THE COURT: All right.

MR. CHILDERS: That it.

THE COURT: All right. Call your next witness.

MR. CHILDERS: Again, I apologize. We have another video. This will be Dr. Abdelgaber. And our play of this, Your Honor, is about 45 minutes long.

THE COURT: Okay.

**VIDEOTAPED DEPOSITION OF AHMED ABDELGABER, PLAINTIFFS' WITNESS, PLAYED.**

(Videotaped deposition paused.)

MR. CHILDERS: This might be a good time for a stretch.

THE COURT: All right. If you want to stand up and stretch where you're seated, that would be fine.

(Pause in proceedings)

THE COURT: How many more minutes on the direct side of this?

MR. CHILDERS: I think about 15 more minutes.

THE COURT: Okay. All right, let's get started.

(Videotaped deposition resumed.)

(Videotaped deposition paused.)

MR. CHILDERS: That's the end of the plaintiffs' direct, Your Honor.

THE COURT: All right.

MR. LEWIS: Your Honor, we'll do the defense play at this time.

THE COURT: You may proceed.

(Videotaped deposition resumed.)

(Videotaped deposition paused.)

MR. LEWIS: Your Honor, that concludes the defense portion.

THE COURT: All right.

MR. CHILDERS: We have again another very short redirect, one minute long.

THE COURT: Go ahead.

(Videotaped deposition resumed.)

THE COURT: All right. That concludes Dr. Abdelgaber's testimony?

MR. CHILDERS: Yes, sir.

THE COURT: All right. This is a good time for us to take a break, ladies and gentlemen. We're going to take a lunch recess for one hour. I'd like you back here at 1:00.

Remember my instructions from last week. Don't discuss the case with anyone or allow anyone to discuss it with you. Make sure you have your stickers as you go and as you depart the courthouse, and then return and please go to the jury room.

All right. If there's nothing else, I'm going to let

the jury go first. I have a matter to take up with counsel as soon as the jury leaves.

(Jury retired from the courtroom at 12:03 p.m.)

THE COURT: All right. You may be seated.

Is there anything else counsel wants to bring to my attention about the pending motion regarding Dr. Ashhab's testimony?

MR. CHILDERS: No, Your Honor.

MR. LEWIS: No, Your Honor.

THE COURT: Well, as I understand it, first, the defendant's written motion sought to prohibit Dr. Ashhab from being asked or giving opinions related to, first, whether the label was inadequate because it did not reveal that Pradaxa had not been tested on patients who had severe renal impairment; secondly, that the label was -- in the opinion that the label was defective because the label did not reflect whether or not testing had been done at the 75-milligram dose.

In response, plaintiffs indicate they don't intend to ask Dr. Ashhab for opinions that would be critical of the label for the absence of that information but, instead, merely intended to ask him whether as a fact he was aware that the label did not address testing for -- on patients with renal, severe renal impairment or testing at the 75 dose.

In response, defendants argue that that would be misleading or confusing to the jury because there would be no reason for Dr. Ashhab to mention those two facts unless he was offering an opinion or an inference critical of the company's labeling.

I agree with the defendant. The Court has reviewed not only the motion but the entire deposition of Dr. Ashhab, as well as his report.

First, I would find -- I accept plaintiffs' representation that they didn't ask -- intend to ask him specific opinions critical of the label. And that certainly wasn't part of his report or even noted in his deposition.

Beyond that, I would find that I agree with the defendants that it would either be cumulative and/or confusing or misleading to the jury for Dr. Ashhab to testify as to the fact about the labels not having this information with the testing.

First, obviously, he didn't even explain in his report or his deposition that he was familiar at that level with the testing. There's other evidence from Dr. Plunkett, as well as the label itself, that establishes what the label had and whether it should have had more information about the underlying testing.

So I think it would be cumulative for Dr. Ashhab to merely note what's already established by the evidence, and

that is that the label does not specifically note that there was no testing of severely impaired renal patients nor testing specifically of the 75 dose.

So I think it would be cumulative and misleading because he's an expert and he's going to be critical of the defendant's product for a variety of reasons which he explains in his report and his deposition.

And I believe it would be difficult for the jury to not also find that Dr. Ashhab is at least implicitly critical of the label in these two respects. And for the reasons I've stated, I think that's beyond the scope of his opinion.

So I would restrict plaintiffs on those areas and expect you to inform him before he testifies.

MR. CHILDERS: Understood, Your Honor. Thank you.

THE COURT: All right. Is he going to be next up?

MR. CHILDERS: Yes, sir. I believe he's in route right now from Charleston, so as long as the traffic is --

THE COURT: Okay. Well, good luck. And then after him, what do you -- any idea how long your direct will take?

MR. CHILDERS: I'm hoping that my direct takes about an hour, hour and a half.

THE COURT: Okay. Who is going to cross him?

MR. LEWIS: I will, Your Honor.

THE COURT: Any idea?

MR. LEWIS: About the same. I definitely don't want to go longer than they do on direct.

THE COURT: All right. Then after him --

MR. CHILDERS: If, if we finish and have time today we have another video to play of a Boehringer employee, Dr. Van Ryn.

THE COURT: All right. I'll see you back here at 1:00.

(Recess taken from 12:08 p.m. until 1:03 p.m.)

(Jury not present.)

THE COURT: Is he out checking on his witness?

MR. MOSKOW: Sorry, Your Honor.

THE COURT: So I'm going to move the sentencing that I had scheduled for later today, so it's no longer a factor. If, if he's not close or ready, if you want to do the video first, you may do so.

MR. CHILDERS: It looks like he's about 10 minutes away.

THE COURT: That's like 10 minutes to get here?

MR. CHILDERS: Yes, sir.

THE COURT: Well, by the time he parks and does things, so let's go ahead and do the video. And then if we have to stay a little bit later, I no longer have the sentencing. So --

MR. LEWIS: We think it makes sense to play the

video all the way through.

THE COURT: Yeah, we will, right.

MR. LEWIS: Thank you, Your Honor.

THE COURT: It's how long?

MR. MOSKOW: Forty minutes total.

THE COURT: Okay, great. Bring the jury in.

(Jury returned into the courtroom at 1:05 p.m.)

THE COURT: All right, ladies and gentlemen, we're ready to resume. The plaintiffs have literally in route one of their expert witnesses, Dr. Ashhab, but he's not quite here yet.

So plaintiffs' counsel has suggested, and I agree, that they proceed with a video deposition that they were going to introduce into evidence anyway. And so that we don't have you all sitting back there waiting 15 or 20 minutes, we'll just proceed with the video.

MR. CHILDERS: Thank you, Your Honor. This will be the deposition of Joanne Van Ryn, a Boehringer employee. And I think our play is around 18 minutes long.

**VIDEOTAPED DEPOSITION OF JOANNE VAN RYN, PLAINTIFFS' WITNESS, PLAYED.**

(Videotaped deposition paused.)

MR. MOSKOW: Your Honor, that concludes the plaintiffs' play of Dr. Van Ryn.

THE COURT: All right.

MR. LEWIS: Your Honor, we'll do the defense play at this time.

THE COURT: Go ahead.

(Videotaped deposition resumed.)

(Videotaped deposition paused.)

MR. LEWIS: That concludes the defense play, Your Honor.

THE COURT: All right. Are we finished with that?

MR. CHILDERS: Yes, Your Honor. We don't have anymore.

THE COURT: All right. Why don't we go ahead and take a brief recess. The next witness is Dr. Ashhab, a live witness?

MR. CHILDERS: That's correct, Your Honor.

THE COURT: And so as to avoid an interruption to that, let's take about a five-minute recess, be pretty quick.

(Recess taken from 1:48 p.m. until 1:53 p.m.)

THE COURT: All right. Are we ready to proceed?

MR. CHILDERS: Yes, Your Honor.

THE COURT: Let's bring the jury out.

(Jury returned into the courtroom at 1:53 p.m.)

THE COURT: All right, plaintiffs may call their next witness.

MR. CHILDERS: Your Honor, plaintiffs call

Dr. Ashhab.

THE COURT: All right.

Dr. Ashhab, if you'll step up here, my clerk will administer the oath.

**HAZEM ASHHAB, PLAINTIFFS' WITNESS, SWORN**

DIRECT EXAMINATION

BY MR. CHILDERS:

Q. Doctor, just so you know, the acoustics in here are not great, so you have to speak into the microphone. Okay?

A. Okay.

Q. Would you please introduce yourself to the jury?

A. My name is Dr. Ashhab. I'm a gastroenterologist specializing in internal medicine and gastroenterology and liver disease.

I'm Board Certified and recertified in gastroenterology. I'm part of a private practice affiliated with the University, WVU, and with Charleston Area Medical Center in Charleston, West Virginia. We are partners of six.

Q. Let me stop you there and sort of break that up a little bit if I could. Do you practice -- you practice here in West Virginia?

A. Yes.

Q. And where is your practice?

A. In Charleston, West Virginia.

Q. And what kind of a practice is it?
A. It's a single specialty practice where all six of us are gastroenterologists or Board Certified in gastroenterology.
Q. Could you explain to the jury what gastroenterology means?
A. So --
Q. We're not doctors, so if you could explain to us.
A. So gastroenterology is the specialty in internal medicine where you deal with patients with digestive disease disorders including the stomach, the bowels, the colon, the liver, the pancreas.

We deal with patients with symptoms related to these organs including problems with swallowing, problems with the liver, and bleeding as well.
Q. That was my next question. Do you treat patients who have GI bleeds or gastrointestinal bleeds?
A. Very frequently.
Q. How often would you estimate you do that?
A. Almost on a daily basis, at least twice a week.
Q. So let me ask you another question. In addition to your medical practice, do you treat patients at hospitals?
A. Yes. We, we are the only group that covers Charleston Area Medical Center, CAMC, including Memorial and General divisions and Women and Children for anybody in relation to

bleeding or gastrointestinal disorders. I do also have privileges and do out-patient procedures at Charleston Surgical Hospital.

Q. Okay. How long have you lived and practiced medicine here in West Virginia?

A. Seventeen years.

Q. You mentioned you were Board Certified; --

A. Yes.

Q. -- is that right? And you have Board Certifications in two different areas of medicine?

A. Gastroenterology is a subspecialty of medicine. So you have to do training and complete your training, get Board Certified in internal medicine, and then you go into gastroenterology as a subspecialty.

Q. What do you have to do to be Board Certified? What does that mean?

A. So you have to go into a training program that is approved and accredited by the American Board of Internal Medicine. And you go through testing and training for a minimum of three years in internal medicine.

And after you pass your exams and evaluations you get a certificate that you are Board eligible. So at this point, you have a certificate that you specialize in internal medicine, and then you go to sit before the Board.

And the American Board is a national exam. Same

questions, same standards are applied to all physicians from coast to coast.

Q. So you have to become Board eligible by education and training and then you take a test to become Board Certified?

A. Correct.

Q. And when did you become Board Certified in internal medicine?

A. In 1994.

Q. And when did you become Board Certified in gastroenterology?

A. In 1998.

Q. And did you have to renew that again?

A. Yes. In 2009 I renewed it and the certificate was issued in 2010. So it is valid for 10 more years. We recertify every 10 years.

Q. Okay. And when you recertify, what do you have to do?

A. You do things all over again. You basically have to, to study. And sometimes you go through courses. Sometimes you do it on-line. And then you go sit for the exam.

Q. Okay. Did you treat patients, gastroenterology patients in Charleston last week?

A. Yes.

Q. How about this week? Did you treat patients today?

A. Yes.

Q. Okay. And I understood --

A. Before coming to court.
Q. And I understood you had a couple maybe that came in unexpectedly and you were there longer than you expected to be this morning?
A. Yes. A gentleman came with bleeding actually last night, so I had to take care of him today.
Q. And then when you leave here after you testify, are you going to go back and treat patients there tomorrow?
A. Maybe even tonight.
Q. Okay. Depending on what time we let you go?
A. Because I'm on call, yeah. I told them 6:00, so I hope I get there before 6:00 but --
Q. Have you ever treated a patient who had a GI bleed who you believed it was caused by Pradaxa?
A. Yes, more than one time.
Q. And you understand that's why we're here today to talk about a patient who had a GI bleed while she was on Pradaxa; right?
A. Yes.
Q. And did you review Betty Knight's medical records in forming your opinions?
A. Yes.
Q. Did you review the depositions of her doctors that were taken in the case before you formed your opinions?
A. Yes.

Q. Okay. I want to walk through a couple of those records with you right now. You have in front of you a binder. If you could go to the tab that's 2000-A, do you see that?

A. Yes.

Q. If you would turn to Page 26 at the top, on the top right corner.

A. Yes.

Q. Okay.

MR. CHILDERS: And, Your Honor, I probably should have done this previously. We have agreed on a comprehensive medical examination exhibit, Exhibit Number 2000. These are taken from that. We'd move 2000 into evidence at this point.

THE COURT: Any objection?

MR. LEWIS: No objection, Your Honor.

THE COURT: It's admitted and it may be published.

MR. CHILDERS: Thank you, Your Honor.

(Plaintiffs' Exhibit Number 2000 admitted into evidence.)

BY MR. CHILDERS:

Q. Do you see, Doctor, this is the History and Physical from May 20th, 2013, for Ms. Knight?

A. Yes.

Q. Can you explain to the jury what a History and Physical is?

A. When a patient comes to the hospital, whether to the emergency room or otherwise, usually a house officer or a specialist or a hospitalist will interview them for the first time.

They will obtain detailed medical history of the patient on why they are coming this time, what pre-existing conditions or medical history they had in the past, review their medications, and then perform a thorough physical examination.

Based on that, they will order some lab testing or imaging test to help them in reaching the diagnosis. And then they put a set of orders regarding management.

And from that point on, the care is directed according to that assessment, whether the patient goes to the floor or to the intensive care unit and so on and so forth.

Q. This particular record is dictated by Dr. Abdelgaber. Do you see that?

A. Yes.

Q. And the jury this morning heard his and watched his deposition. He talked about this record, so I don't need to go in great detail with you. But if you could, tell us what was the reason why Ms. Knight was going to the hospital that day?

A. Because she experienced GI bleeding. She had blood mixed with her stool and that made her feel weak, went to

her doctor. She had blood and lots of blood clots.

Q. Okay. And in your experience, is that the kind of GI bleed that you would treat?

A. Yes.

Q. And as you reviewed the records, did you also see that -- how long she stayed in the hospital for that particular visit?

A. I believe over two weeks.

Q. Okay. And if we could, I want to take you to Page 32 in that same exhibit. Do you see this is a Discharge Summary from that hospitalization?

A. Yes.

Q. Okay. And tell the jury, if you would, what's the purpose of a Discharge Summary?

A. It summarizes the, the hospital stay of the patient including when did they come in, how did they progress during the hospital stay, and what is their final plan of disposal.

And it should reflect whether the patient had medications, blood transfusions, surgeries or procedures. It should reflect the outcome, whether the patient gets better or worse.

Q. Okay. And if you could, if we could look at the Discharge Diagnoses.

Could you call up the first three?

What were the, the diagnoses, the first three diagnoses on this Discharge Summary?

A. Severe gastrointestinal blood loss anemia, was symptomatic initially; lower gastrointestinal blood loss, likely colonic AVM bleeding, status-post colonoscopy and clipping. Number three is atrial fibrillation on Pradaxa.

Q. Okay. Do you see anything in this Discharge Diagnoses that mentions Plavix?

A. No.

Q. Okay. And then I want to sort of get a general -- ask you a general question and then we can sort of walk through the records to get more information.

Based on what you have reviewed in all of the records, Doctor, and the depositions that you read and your training and experience as a gastroenterologist, have you formed any opinions on what was the most significant cause of Betty Knight's gastrointestinal bleed in May of 2013?

A. Most likely, the severity of her bleeding was related to the intake of Pradaxa.

Q. And have you -- and based on the records you've looked at, and we'll break it down after we talk about it more generally, did you form any opinion on whether or not she was over-anticoagulated or had too much Pradaxa in her blood?

A. I believe she did.

Q. Okay. Well, let's start with Betty herself as a patient. What is it about Betty Knight that would lead you to believe that she's a patient who would likely be over-anticoagulated on Pradaxa?

A. Well, she has the risk factors for having too much of the drug in her system, including her age, above 65, -- in her case she's above 80 -- a female, has compromised kidney function test.

Also in this particular incidence one of the medications she was taking, namely Coreg, would have affected the level of her blood thinner, the Pradaxa, by making more of the blood -- of the medication stay in her system being a P-gp inhibitor.

Q. The jury has heard that term and I actually put the board back up for them just in case while we're doing this examination. Could you explain, as best you can, what does that mean if a drug is a P-gp inhibitor?

A. Well, P-gp stands for permeability glycoprotein. So this is like a vehicle that transports certain medications across membranes between cells in the plasma.

So if that vehicle is interrupted, it's not going to carry the medication where it's supposed to go. So if you have -- the studies have found that certain medications that inhibit that vehicle or make it not work will result in some of these medications being too high in the system or too

high in the blood, so they are not eliminated properly. That may lead to a high level in the blood.

It has also been associated with other conditions that may not be relevant to this, but it can also affect your body response to certain antibiotics. So some people will not respond to certain antibiotics because of problems with that transporter. So it's an important vehicle in the, in the human body.

Q. Okay. And so if I understood you correctly, the, the things about Betty that make you think that she's likely to be over-anticoagulated were that she's over 80; she's a female; she had severe kidney impairment; and she was taking Coreg, which is a P-gp inhibitor drug. Is that right?

A. That's correct.

Q. What -- do you how what Coreg is used to treat?

A. It's a beta blocker. It's used for blood pressure and rapid heart rate in people with heart disease.

Q. Is that common medication that you would see in an atrial fibrillation patient?

A. Yes.

Q. Beyond Betty herself, did you see any test results or anything in the medical records that indicated to you that Betty had too much Pradaxa in her system when she had this bleed in May of 2013?

A. Well, unfortunately, there wasn't any precise test

given to measure Pradaxa. However, the closest or the rough blood test that was available and mentioned in her records is called the aPTT which seemed to be significantly elevated, although the record reflects that she had stopped taking the medication more than 24 hours prior to the test and she had received a blood transfusion which should have helped in correcting that abnormality but instead was elevated. So I would say it must have been overly anticoagulated.

Q. Okay. And so if we could just sort of break that down a little for the jury, she had an aPTT test which we've got that on the board too. That's one of these coagulation tests you can give a patient; is that right?

A. That's correct.

Q. And that test wasn't given right when she came in the hospital; is that correct?

A. It seems that it was done more than 24 hours after that.

Q. Okay. It was the second day she was in the hospital?

A. After she received blood transfusion.

Q. Why is that important as far as testing the level of coagulation in her blood that it was more than 24 hours after her last Pradaxa dose?

A. Well, because you, you would, you would think, I mean -- well, not you would think. You know that if you

have not taken the medication for so long, the medication level should have been down significantly or eliminated most of it depending on the half-life.

So if you go back 24 hours prior or you do the test when she actually took the medication, then it will be much higher than what you measure 24 hours later.

Q. Okay. And in this case, they just happened to not measure it the day she came in; is that right?

A. That's what we have in the record.

Q. Okay. What about the amount of bleeding she had? Was there anything about that that factored into your opinion on whether she was over-anticoagulated?

A. Well, it was a life-threatening bleed. She had lost almost -- more than five grams of hemoglobin. It went down to a hemoglobin of 6. That's life-threatening. She had acquired a total of four units of blood transfusion. I would say, you know, that's life-threatening.

If you put these two factors in somebody who's not 40 or 50, who's 83 and has heart disease and has diabetes and has had a stroke, you better believe it's life-threatening.

Q. Okay. You mentioned that we didn't have a precise measurement of Betty's Pradaxa level. Do you recall that?

A. That's correct.

Q. And as a doctor who treats patients with GI bleeds, does Boehringer provide you with any information as to how

you -- in the label, in the Pradaxa label as to how you can measure precisely the amount of Pradaxa that a bleeding patient has when they come in?

A. No.

Q. Without Boehringer providing that information to you, is there any way for us to know exactly how much Pradaxa Betty had in her blood when she had this GI bleed?

A. No.

Q. Were you aware that Boehringer tells doctors like you in Europe exactly how to measure Pradaxa blood levels?

A. I believe they have more information in Europe than they do in the United States.

Q. Is that the kind of information that you would believe would be helpful to you in treating patients here in West Virginia?

A. Definitely.

Q. And how would that help you?

A. Well, it would help me identify who is at higher risk of bleeding, whose level is too high because of these risk factors. So I may tell them to reduce the dose or not take the medicine or find another drug to use.

Q. Some drugs aren't right for everybody. Is that fair to say?

A. That's correct.

Q. You mentioned that, that Betty had what you call a

life-threatening GI bleed; is that right?

A. That's right.

Q. Are there different ways you categorize them as a doctor who treats GI bleeds as far as how bad they are?

A. Yeah. Well, you get the patient who comes in walking and talking to the office and has passed some blood through the rectum. They have normal vital signs and normal hemoglobin. So that's minor.

A major GI bleed would be when they bleed probably a couple units of blood. They may have rapid heart rate so they are a little bit hypertensive, but they do not necessarily need a blood transfusion. They may or may not. But usually it is less than four units, maybe one or two units.

We call that a major GI bleed because we see a drop in hemoglobin, typically one to two grams, maybe with a little bit of low blood pressure. So these are some of the criteria.

And then the life-threatening one is the one we talked about when you need four units of blood or more. Usually you have low blood pressure. You may have changes in mental status. An elderly person may be confused.

And in addition, you know, a hemoglobin drop of more than five grams, that's life-threatening.

Q. Okay. You reviewed the Pradaxa labels, right, the

physician label in this case?
A. Yes.
Q. And, in fact, more than one as they changed over time?
A. Yes.
Q. If you could look in the binder you have in front of you, the first exhibit, which is Number 86.
If you could call up the third page of Exhibit 86.
MR. CHILDERS: Your Honor, I believe this is already admitted.
THE COURT: I'm sorry?
MR. CHILDERS: This is an already admitted exhibit. I apologize, Your Honor.
THE COURT: Right.
MR. CHILDERS: Okay.
BY MR. CHILDERS:
Q. Do you see on Page 3, Section 6.1 that talks about clinical trial experience?
Would you call up that middle paragraph just above Table 2. It's just called the "bleeding" paragraph. Okay.
Do you see it here that -- I'm going to ask you questions while she gets that ready.
Do you see in here that this is talking about the RE-LY study that was the pivotal clinical trial for getting Pradaxa approved for atrial fibrillation patients?
A. Yes.

Q. Do you see that? And in here do you see that they say, "This is how we define in the RE-LY study if someone had a major bleed or a life-threatening bleed." Do you see that?
A. Yes.
Q. And there about midway through the paragraph do you see where it says, "A life-threatening bleed met one or more of the following criteria"?
A. Yes.
Q. Do you see that?
A. Yes.
Q. And the third item in there is reduction in hemoglobin of at least five grams per deciliter. Do you see that?
A. Yes.
Q. Did Betty have that?
A. Yes.
Q. Okay. And the second one is transfusion of at least four units of blood. Do you see that?
A. Yes.
Q. And did Betty have at least four units of blood transfused?
A. Yes.
Q. So she met two of the criteria, not just one, for a life-threatening bleed if she had been in the RE-LY trial; right?
A. And I would argue on a third one too.

Q. Okay.
A. It depends on how you look at it. Necessitating surgical intervention, which she had colonoscopy and clipping.
Q. Okay.
A. Before the area of colonoscopy and clipping, she would go to surgery to have that part of the colon removed. So it depends on how you look at it, but that's another fact.
Q. All right. And so not only in your experience it's a life-threatening bleed, the company actually says that as well as how they define it in the RE-LY trial?
A. That's true.
Q. Okay. All right. I want to talk to you about -- go back to the actual hospitalization in May of 2013. And if we could look again on Page 32 which was the Discharge Summary we were looking at just a few minutes ago. Okay?
A. Okay.
Q. Do you see there it says at the bottom, "Patient was admitted and given two units of blood for a hemoglobin of 6"?
A. Yes.
Q. Okay. Can you, can you tell the jury, what is a hemoglobin of 6? What does that mean to you?
A. Well, that's a very low hemoglobin. The hemoglobin is the major protein in your blood that carries the oxygen to

the vital organs. So if you want your lungs to have oxygen, your brain to have oxygen, your heart, your kidneys, you need normal hemoglobin or a hemoglobin within one to two grams of the normal.

Once you get to very low levels of hemoglobin, then you don't have the vehicle to deliver oxygen to your tissues, mainly the vital organs. And the brain is one of the most important organs and the kidneys as well. They are very sensitive to hypoxemia, meaning low oxygen in the blood.

Q. Okay. And what's a normal hemoglobin in a patient?

A. It can vary a little bit in the population in the test, the lab that does it, but females usually 12 to 14 and males 14 to 16. So --

Q. So this is half of what you would expect it to be?

A. I would say so.

Q. And, and what does that mean to you when you see that?

A. So you have somebody who's really in a life-threatening situation where they don't have enough means to deliver oxygen to the vital organs. So these people would be at high risk for, you know, ischemic stroke, an insult to the heart, insult to the kidneys with this level of hemoglobin.

Q. Okay. And then we go on and see here it says she was evaluated by GI who took her for upper and lower endoscopies. An AVM of the colon was actively bleeding which was clipped. Do you see that?

A. Yes.
Q. Are those the procedures that you perform as well in your practice?
A. Yes.
Q. Okay. Could you tell the jury what, what is an AVM?
A. It stands for arteriovenous malformation which is basically an abnormal tiny vessel in the wall of the colon or the intestine that can easily bleed upon the blood being too thin or on friction or trauma.

So instead of having the normal vessels that taper down into the capillaries and meet together to transport from artery to vein, they actually make a little pooling of these capillaries. And that pooling of these little tiny vessels, because it's very thin and abnormal, is high risk for bleeding.

Q. Have you treated patients who have AVMs that don't bleed?
A. Yes.
Q. Do most AVMs bleed or not bleed?
A. No, most of them do not bleed.
Q. Okay. When is it that you most often see a bleeding AVM?
A. When people are taking what we call a blood thinner. Usually it's an anticoagulation medication that makes the blood too thin.

Q. Okay. If we could go on in this report, again do you see it says, "Her hemoglobin improved with two units of blood. She was given another two units for a total of four units." Do you see that?

A. Yes.

Q. Okay. And is that an unusual amount of blood to have to transfuse for a patient, four units?

A. It's a lot, but for somebody with a hemoglobin of 6, that's what you need.

Q. Okay. And then it says her hemoglobin went up to 10.8. Is there anything about Betty's physical condition that would make you think that that is probably a normal range for her to have a hemoglobin?

A. I would say, you know, 10 to 11 is okay for her because she has chronic kidney disease. So people with chronic renal failure usually tend to have a little bit lower hemoglobin and their body adjusts to that.

Q. And that baseline becomes just a little bit lower?

A. Yes.

Q. Okay. Betty was taking some other medications at the same time she had this bleed besides Pradaxa; correct?

A. Correct.

Q. Do you believe any of the other medications that she was taking played any part in the bleed?

A. She's on -- she was on two anti-platelet agents. I

recall aspirin and Plavix.

Q. What's the difference between an anti-platelet agent and an anticoagulant drug?

A. Okay. So the anti-platelet will inhibit the platelets that are usually running in your system from making an aggregate or a clot that will block an artery while the anticoagulants make your blood in general very thin.

Q. And how does that affect -- if someone is having a bleed or has damaged tissue, how do those two work together?

A. So the, the aspirin and Plavix will, will make you more likely maybe to ooze a little bit of blood. It's kind of like a faucet dripping water.

But the blood thinners may make you just having an open hose. Because the blood is too thin when it bleeds, it doesn't stop.

So you get one trickling faucet and one that's got an open faucet. The anticoagulants is the open faucet where the blood is too thin, and when it bleeds it doesn't stop. And the aspirin and Plavix is like the trickle.

Q. Okay. What role do you believe the Plavix and aspirin, if any, played in the bleed that Betty had?

A. Well, they're probably a contributing factor.

Q. Okay. You, you mentioned earlier you thought Pradaxa was the most substantial factor. How would you rate the Plavix and aspirin as opposed to Plavix as being likely

causes of the bleed?

A. Well, in our experience in gastroenterology, two things we, we notice in our practice; number one, the location of the bleeding and, number two, the amount of bleeding.

So with aspirin and Plavix you are more likely to see bleeding from upper gastro-intestine, let's say the stomach and maybe the duodenum, while with anticoagulants, especially Pradaxa, you are more likely to see the bleeding coming from the lower GI tract, mainly the colon.

Q. And where was Betty's bleed?

A. It was in the colon.

Q. Okay. The lower GI?

A. Lower GI. And then the second point is usually with aspirin and Plavix, you may bleed as an ooze, a little bit at a time, and it takes you a long time before your hemoglobin drops, while when you bleed -- if you have a lesion and it bleeds with anticoagulants, and Pradaxa is one of the higher risks for that, the bleeding is massive. They come in passing clots, a lot of blood.

So the amount of bleeding is more with anticoagulants and the location is lower GI and colon.

Q. If you had a patient who's at high risk of bleed, they come to you and, you know, you say this patient is at high risk of bleed and they're on all three of those medications and you want to take them off just one of them because

you're worried about the bleed, which one are you going to take them off of - Pradaxa, Plavix or aspirin?

A. Now, from the gastrointestinal point of view, I probably would have them stop the Pradaxa or look for an alternative. Now, that's from my department, my part.

Now, there are other reasons for the other medications and their cardiologist usually is to make the call.

Q. Well, let's, let's look, if we could, if you look on Page 37 of the binder in front of you.

And if you could call that up.

This is a consult with Dr. Linsenmeyer. Do you see that?

A. Yes.

Q. And it was after Betty had had her bleed. It was about a month after she got out of the hospital. Do you see that?

A. Uh-huh.

Q. Okay. And he mentions here in the first paragraph that -- toward the bottom --

If you could call that up.

Do you see that he mentions that she had been in the hospital with new onset GI bleeding? Do you see that in the first paragraph of the history of present illness?

A. Yes.

Q. Okay. And it goes on to say that she had this AV malformation, had to stay in the hospital until June 8th,

and then went home. Do you see that?
A. Yes.
Q. Okay. If we could turn to the -- three pages in. It's Page 3 of three, 39 at the top. And I want to direct you down to the "Plan" section. Do you see that?
A. The "Plan," yes.
Q. Yes, sir. And this is -- Dr. Linsenmeyer is a cardiologist. Are you aware of that?
A. Yes.
Q. And do you see he says he would not anticoagulate her with recent gastrointestinal bleed. Do you see that?
A. Yes.
Q. And then he goes on a little bit farther down the last -- the second to last sentence he says, "We will resume Plavix in the event she needs cardiac catheterization and hold Pradaxa." Do you see that?
A. Yes.
Q. Is that consistent with what you just told us about which of these drugs you would be most afraid of causing a bleed for this patient?
A. Yes. In her case I would stop the Pradaxa as the --
Q. And that looks like what Dr. Linsenmeyer was saying as well; right?
A. Yes.
Q. Okay. Have you treated patients who are on warfarin,

Coumadin --

A. Yes.

Q. -- who have GI bleeds?

A. Yes.

Q. Okay. In your experience when those patients have a GI bleed, what do you normally find as far as their INR number? Is it normal? Is it elevated?

A. Usually very high.

Q. Okay. And when you say very high, what do you mean?

A. Probably about -- above 10.

Q. Okay. How often do you see GI bleeding in a warfarin patient who has -- who's in therapeutic range, who's in between that two and three number?

A. It's not common as a known agent.

Q. It's possible; right?

A. Yes, but it's not common.

Q. Okay. Do you believe that Betty would have had a severe GI bleed in May of 2013 if she had still been on warfarin or Coumadin instead of Pradaxa?

A. I would think not, not a life-threatening bleed because she's been on Coumadin before and it was therapeutic and supratherapeutic, but she never had the life-threatening bleed before on Coumadin.

Q. Is there anything about Pradaxa -- is it -- do you know whether or not Pradaxa is more likely to cause a GI bleed

than Coumadin?
A. We do.
Q. What, what do you know about that?
A. Well, from our experience, it's more than double. I mean, it's significantly higher than warfarin to cause GI bleeding, Pradaxa is.
Q. Okay. You mentioned that Betty did not have a life-threatening bleed while she was on Coumadin.
A. She didn't.
Q. All right. I want to talk about that because the jury's sort of heard mixed signals on that. I want to clear that up. Okay?
A. Okay.
Q. First of all, Betty had -- we already talked about this. She had chronic kidney disease; right?
A. Correct.
Q. And you told us that affects her hemoglobin and you would expect it to be a little lower than normal anyway?
A. Correct.
Q. What the jury has heard is that Betty -- Betty had to be taken off Coumadin at some point and it was potentially because of a GI bleed. Okay?
I want to show you records from November of 2008 where Betty was actually taken off the warfarin. Okay?
If you look in your binder at the very beginning of

this same Section 2000-A, do you see that? Go to the first page. It's got the sticker on it. Do you see this is another History and Physical? This one is from November 13th, 2008.

A. Correct.

Q. Okay. I want you to look at this H & P, the history of present illness, and tell me is there any mention of a bleed in there?

A. I don't see any.

Q. Okay. Why don't we turn the page, if you would, with me. And there is a section called "Review of Symptoms."

A. Yes.

Q. Okay. And what's a Review of Symptoms? Could you tell the jury what that section means?

A. That after you complete the main reason the patient came to the hospital and you get the detailed story of that, then particularly in elderly people with multiple medical problems, you go on a system by system asking them about their neurological function, their breathing, their heart, their intestines, their genitourinary tract, and their musculoskeletal.

So you're reviewing each and every system to make sure that you covered everything and you did not miss anything in, in what the patient told you. So it's basically a review of each and every system in your body.

Q. Do you see here that the GI is listed as a separate system?
A. Yes.
Q. What does it say next to GI?
A. "No melena, hematochezia, nausea, vomiting, or diarrhea."
Q. Can you tell the jury --
A. "She has chronic constipation and reflux."
Q. Sorry. I didn't mean to interrupt you. Can you tell the jury, what is melena?
A. Melena is transported blood that usually appears dark in color, almost black, because it's blood that has, that has passed through your gastrointestinal tract. So it gets partially digested by certain enzymes. So the blood changes color from bright red to dark. We call it melena. It's a reflection of GI blood loss basically.
Q. So when it says no melena, what does that mean to you?
A. That she did not have symptoms of passing blood at rectum or passing blood that she could see.
Q. And the next one is that she didn't have hematochezia; is that right?
A. Hematochezia is when you pass blood through the rectum.
Q. So if it says no hematochezia, what does that tell you?
A. There was no bleeding that she could see.
Q. Okay. And then if we could turn two more pages, you

see -- and this would be Page 4 at the top. Do you see that this is a consult a couple of days later by Dr. Haberman?

A. Yes.

Q. And you understand him to be a cardiologist as well?

A. Yes.

Q. Okay. And do you see -- in this history of present illness do you see anything that says she's having a bleed?

A. I, I don't see.

Q. Okay.

A. If you can point it out to me, but I don't see any.

Q. Okay. And then if we look on the next page, there's a section called "Impression." Do you see that down toward the bottom?

A. Yes.

Q. Okay. And, actually, can you pull up the paragraph above it as well?

Just above "Impression" do you see the very last sentence in the diagnostic data it says the INR is therapeutic at 3.3? Do you see that just above the Impression, the word "Impression"?

A. Yes.

Q. What does that mean that the INR is therapeutic?

A. The INR is a lab test we use to monitor the degree of anticoagulation when a patient is on Coumadin. And we look at studies that tell you where your INR level should be.

So, for example, if somebody has atrial fibrillation like Mrs. Knight and you want to prevent a stroke, typically you like it to be between 2.5 to 3 or 2.5 to 3.5, in that range.

And if somebody has a heart valve, the numbers may be a little bit different. But we use that blood test to tell us how thin the person's blood is and to adjust their Coumadin dose.

Q. When you see in a medical record it says that the INR was therapeutic, what does that tell you as a doctor?

A. I'm assured that the patient is taking the proper dose of the medication.

Q. Okay. She's not over-anticoagulated? Is that fair to say?

A. No. It's therapeutic, so it's where she should be.

Q. Okay. And then if we look under "Impression," do you see Number 3 says anemia which might be secondary to the recent initiation of Coumadin. Do you see that?

A. Yes.

Q. Does it say anything in this Impression about a bleed, a GI bleed?

A. It does not.

Q. And then under "Recommendations," the first thing is they're going to stop the Coumadin. Do you see that?

A. Yes.

Q. If we could just go to the next page, yes, the following Page 6, there's the, the fifth recommendation.

Do you see that it says, "I'm hopeful that the transfusion will help with the heart rate which may be a response to anemia"?

Do you see that?

A. Yes.

Q. What does that mean to you?

A. That she was having tachycardia and he thought that the tachycardia, the rapid heart rate was because she had low hemoglobin, did not have enough blood. So he said if we give her blood, maybe that will help heart rate slow down a little bit and be close to normal.

Q. Okay, all right. I want to move on to the next page which is the following, the following day. Do you see that this is a consultation from Dr. Rohrbach?

A. Yes.

THE COURT: Excuse me.

Doctor, could you pull the microphone down just a little? When you look down at the medical record, it's not picking you up. Thank you.

BY MR. CHILDERS:

Q. Do you see this is a consultation from Dr. Rohrbach?

A. Yes.

Q. And if we go to the Impression on the next page, he

says, "Anemia. This certainly does need to be evaluated given her long-term need for anticoagulation. We'll start her workup with an upper endoscopy. And if this is unremarkable, at some point she probably will require a colonoscopy as well."

Do you see that?

A. Yes.

Q. And could you tell the jury what an endoscopy is?

A. Endoscopy is the test by which we take a flexible tube with a camera at the end and go in the mouth down the food tube, the esophagus into the stomach.

We pass the stomach into the first part of the small intestine called the duodenum looking for abnormal lesions like a bleeding source, ulcer, or cancer or a stricture.

Colonoscopy is when you take a different tube, longer usually, with a camera at the tip and you go through the rectum into the entire large intestine, and then where the junction between the small intestine and the colon is.

Again, the colonoscopy is designed to look for abnormal lesions in the colon like colon polyps and colon cancer, AV malformations, bleeding source, inflammation, diverticulosis, all that.

Both tests have, have abilities for diagnosis as well as a therapeutic option; for example, to remove polyps to prevent cancer or to clip a lesion and stop bleeding. So

they are used as diagnostic and therapeutic tools.

Q. Okay. And if we turn three pages in this record to Page 11, do you see where that upper endoscopy was actually performed two days later?

A. Yes.

Q. And what was the -- did they find any blood, first of all? Do you see the part right in the middle that says "no blood was noted"?

A. Yeah. It says "normal upper endoscopy."

Q. What does that mean if it's a normal endoscopy?

A. That they found no lesions to report.

Q. Okay.

A. No bleeding, no ulcers, nothing to report.

Q. And then I want you to flip back two pages. And do you see that there was a cardiac catheterization that was performed the day before that?

A. Yes.

Q. Is that an invasive procedure?

A. Cardiac catheterization, yes.

Q. Is that a procedure where you would have a patient stop taking their anticoagulant before you performed it?

A. Yes.

Q. Okay. And so in this particular case, she's off Coumadin and they perform a catheterization and put in stents; correct?

A. Yes.
Q. Okay. And then I want you to look at "Plan" on the very, the next page, Page 10, the very last one, Number 6 in "Plan." Can you see it says, "The decision of whether to restart the Coumadin will be left to Dr. Haberman."
Do you see that?
A. Yes.
Q. So you have to stop Coumadin before you have a cardiac catheterization like she had; correct?
A. Yes.
Q. And then this doctor, in particular Dr. Gunnalaugsson, is saying, "I'm going to leave that up to another doctor to decide whether or not to put her back on the Coumadin." Right?
A. Yes.
Q. Then I want you to turn to Page 12 in this record which is the Discharge Summary. Do you see that?
A. Yes.
Q. You told us what a Discharge Summary is. So I want, I want to ask you, do you see anything -- and there are 24 items listed on her Discharge Diagnosis; correct?
A. Yes.
Q. Is any one of those GI bleed?
A. No.
Q. Okay. The jury also heard that -- has heard that Betty

got a clot in her arm after she stopped the Coumadin in November of 2008, that she got a clot in her arm in February of 2009. Do you recall from the medical records seeing that that occurred?

A. Yes.

Q. All right. I want to direct you to another record, Page 52 of this particular set we're looking at now. Let me know when you're there.

A. 52?

Q. Yes, sir.

A. Yes.

Q. Do you see this is a consultation from a Dr. Baryun on February 10, 2009?

A. Yes.

Q. So just a few months after the record we just saw; correct?

A. Yes.

Q. And the reason for the consultation is bradycardia; right?

A. Yes.

Q. And then if we look under "History of Present Illness" about midway down, do you see it says, "Patient has been on Coumadin in the past. However, it was held because of the percutaneous coronary intervention and was not restarted." Do you see that?

A. Yes.
Q. Is that percutaneous coronary intervention the cardiac catheterization we just looked at?
A. Yes.
Q. Does it say anything in this record about her having a bleed, whether it was acute or chronic, and that's the reason why Coumadin was stopped?
A. It does not. It says it was stopped because of the PTC, the percutaneous intervention with the catheterization.
Q. I want you to turn now to -- sorry. I'm making you skip around here. If you go to Page 23 of this same set of records, you should find another consultation that was three days after that, February 13th, 2009. Do you see that?
A. Yes.
Q. And at this point, Betty's not on Coumadin; right?
A. Correct.
Q. She had been taken off of it. And do you see what it says under his "History of Present Illness," the first sentence? Do you see it says, "The patient is a 79-year-old white female seen in consultation at the request of Dr. Dawn MacFarland for evaluation of anemia." Right?
A. Yes.
Q. Anemia, you told us, is where the hemoglobin is a little low and you want to find -- try to find out why; correct?

A. Yes.
Q. At least that's what they're doing here. And at this point if you look under "Medications," there are 15 things listed, not one of which is Coumadin or warfarin.
A. Yes.
Q. Okay. And then if we turn to the next page, do you see a section that's called "Diagnostic Data"?
A. Yes.
Q. And under that do you see that she had labs checked and that her hemoglobin had dropped to 9.1? Do you see that?
A. Yes.
Q. That's pretty -- almost exactly what it was in November of 2008 when they took her off Coumadin; correct?
A. Yes.
Q. Okay. But at this point, she's not on Coumadin; right?
A. Right.
Q. And she's diagnosed with anemia; right?
A. Yes.
Q. Okay, all right. I want to get into now, if we could, the Pradaxa label that was in effect when Betty Knight was started on Pradaxa. Did you review that label?
A. Yes.
Q. Okay. And the jury saw this morning that the label that Dr. MacFarland had available to her was Exhibit Number 86 in your binder, the label that was revised in March of

2011, if you would turn to that with me.

Do you see on the front page, the very first page what's called the "Highlights of Prescribing Information"?

A. Yes.

Q. And at the -- and in the very right column, the top half, is there a section there called "Drug Interactions"? Do you see a section called that?

A. No.

Q. Do you see anything in this "Highlights of Prescribing Information" that tells a physician that a patient who has severe renal impairment and is taking a P-gp inhibitor should not get Pradaxa?

A. No.

Q. Okay. I want you to turn to the third page. And at the bottom there's a section called "Drug Interactions." Do you see that?

A. Yes.

Q. And when you look at that section, is there anything there that tells a physician that a patient with severe renal impairment who's taking a P-gp inhibitor should not take Pradaxa?

A. No.

Q. Okay. You told us earlier Coreg is a P-gp inhibitor; right?

A. Yes.

Q. And it's a drug that is commonly taken by patients who have AFib; correct?
A. Yes.
Q. Was Betty taking that drug when she started Pradaxa?
A. Yes.
Q. I want you to look back on Page 2 there is a section 5.3 at the very bottom of this label. And you see it's called "Effect of P-gp inducers inhibitors on dabigatran exposure." Do you see that?
A. Yes.
Q. Okay. And that's what we're talking about. Coreg is a P-gp inhibitor; right?
A. Yes.
Q. Is the word "Coreg" or the chemical name "Carvedilol," are either of those in this label at all?
A. No.
Q. All right. I want to turn now to a change that was made in the label after Betty started taking Pradaxa. Okay?
If we could look at Exhibit 88 which is the label as it was revised in January, 2012. Betty is already on Pradaxa. The decision had already been made to put her on it. Do you see that?
A. Yes.
Q. Now, when we look at this section in the "Highlights of Prescribing Information --"

I'm sorry. Let's take that down.

MR. CHILDERS: I apologize, Your Honor. I thought that was already in evidence. I would move Exhibit 88 into evidence.

THE COURT: Any objection?

MR. LEWIS: No objection, Your Honor.

THE COURT: It's admitted and may be published.

MR. CHILDERS: Thank you, Your Honor.

(Plaintiffs' Exhibit Number 88 admitted into evidence.)

BY MR. CHILDERS:

Q. And that particular label -- if we could put it back up -- sometimes I get a little ahead of myself. Sorry.

Do you see now there's a section that's been added called "Drug Interactions"?

A. Yes.

Q. Okay. And the third item in that section says, "P-gp inhibitors in patients with severe renal impairment Pradaxa use is not recommended."

Do you see that?

A. Yes.

Q. Then if we turn to Section 5.3 which is on the third page of the label -- if we could blow up 5.3, that whole section. Okay.

Do you see the little line along the edge? It's a straight line going down next to the second two paragraphs

in this section. Do you see there's a little line there next to it?

A. Yes.

Q. Okay. That information was not -- the part that's in this, these two paragraphs was not in the label we just looked at from when Betty started taking Pradaxa; correct?

A. That's correct.

Q. And then at the very last sentence, again it says, "Avoid use of Pradaxa and P-gp inhibitors in patients with severe renal impairment." Correct?

A. Yes.

Q. It doesn't say avoid certain P-gp inhibitors in Pradaxa. It's just P-gp inhibitors in general. Correct?

A. Yes.

Q. Okay. I want to take you to one more part in here, the very next page. There's a drug interaction section again. Do you see that?

A. On Page 4 you said?

Q. Yes, sir, the very next page, Page 4.

A. Yes.

Q. And here at the very bottom do you see the sentence that says, "The concomitant use of Pradaxa and P-gp inhibitors in patients with severe renal impairment should be avoided."

Do you see that? It's the last, the last sentence in

that section of Drug Interaction.

A. Page 4?

Q. I'm sorry, Page 4, Section 7.

A. Section 7. Yes, I see that. Yes, that's correct.

Q. These changes that we just looked at in this label, as a doctor would you consider those to be significant changes to the label?

A. Yes, very much so.

Q. And as a doctor, what would you expect the drug company to do when they make significant changes like this to a drug label?

A. They contact the doctors, the pharmacists, and -- the pharmacies and sometimes even the patients.

Q. And how do they do that? Do they send letters? Do they call them? What do they do?

A. They send a letter with a big label on it that says "Warning" in red. And, and they mention these changes and they usually are highlighted.

And then often we get calls from the pharmacy saying that we got an update on this medication by the manufacturer and your patient is taking this and this medication and I think they shouldn't be together, so you have to choose between the two. So we get it in more than one way.

Q. And in this particular case having reviewed the evidence about what happened with Ms. Knight, do you know --

the company never sent a letter like that to Dr. MacFarland; correct?

A. To my knowledge, they did not.

Q. One more section I want to look at here with you on Page 2 of this document. It's called "Dosing Adjustments." Do you see that?

A. Yes.

Q. And, again, it's got a little line there saying they've made some changes here. Do you see that? The line that goes along the side of it on the left-hand side?

A. Yes.

Q. Okay. This tells the doctor what dose you should give to your patient; right?

A. Yes.

Q. Does it say anything in here in this dosing section to tell a doctor, "Don't give Pradaxa to a patient with severe renal impairment if they're already taking a P-gp inhibitor"?

A. No, it does not.

Q. Do you recall reading Dr. MacFarland's deposition in preparation for -- or in forming your opinions in this case?

A. Yes.

Q. And do you recall she was asked all kinds of questions about how difficult it was on occasion to keep Betty Knight in INR range?

A. Yes.
Q. If Pradaxa is not an appropriate medication for anticoagulation for a patient, what difference does it make if you have to adjust their warfarin if they can't go on Pradaxa anyway?
A. Not much. It's a little inconvenience, but the patient will come to the doctor and have the INR done if need be.
Q. Okay. Based on what you see in the label as it was changed after Betty had already been started on the medication, would you agree that it's not an appropriate medicine for her?
A. It should have been stopped, no.
Q. And in order for the doctor to know that change has been made, the drug company has to take some affirmative action to tell them; correct?
A. That, that's correct.
Q. You get letters like that; right?
A. I do.
Q. Okay, all right. I want to talk to you now about what happened to Betty after she had the bleed. Okay?
A. Okay.
Q. If we could go back to this section 2000-A, go to the 34th page. Let me know when you're there.
A. Page 34?
Q. Yes, sir. Do you see this is the Discharge Summary

from June 8th when Betty got out of the skilled nursing portion of the hospital?

A. Yes.

Q. Okay. And the first diagnoses was the admitting diagnoses and the discharge diagnoses. It says, "General debility stemming from various medical problems including," it says, "chronic anemia stemming from severe gastrointestinal blood loss due to an AV malformation."

Do you see that?

A. Yes.

Q. Do you recall from Dr. Abdelgaber's testimony he said that word actually should say "acute anemia?" Do you recall he said that?

A. Yes.

Q. And do you agree with that based on your review of the records?

A. Yes.

Q. Between the hospital and the skilled nursing center, Betty was in -- Betty was in their care at St. Mary's for about three weeks; right?

A. Correct.

Q. In your experience, is that an unusual amount of time for someone to have to be in a hospital for a GI bleed?

A. Yes, it's too long.

MR. LEWIS: Objection, Your Honor, leading.

THE COURT: I'm sorry?

MR. LEWIS: He's doing a lot of leading here in the last few minutes.

THE COURT: He's an expert, but don't lead him about matters like that.

MR. CHILDERS: Sure. Sorry, Your Honor.

BY MR. CHILDERS:

Q. In your experience, how does three weeks in a hospital compare for a GI bleed patient?

A. Usually people with simple gastrointestinal bleed stay just for a couple of days. When the bleeding is life-threatening, it's expected they stay longer than a couple of days, maybe five to seven days.

But when people have a life-threatening condition and they also have co-morbidities, it may take them longer. But usually in this day and age a hospital stay more than a week is considered too long unless there are things going on or surgeries or other complications. But for a gastrointestinal bleed, staying in a hospital for two to three weeks is too long of a period.

Q. Where it says on that diagnoses that we just saw, it said "general debility." Do you recall it said that?

A. Yes.

Q. What does that mean as far as what was going on with Betty Knight at that time?

A. At the time of discharge you mean or admission or --
Q. During that time where she was -- why does that -- okay. First of all, it's in the diagnoses. So my question to you is what does that mean so we can explain to the jury?
A. Well, you have someone with multiple medical problems, elderly person, and they get an insult on top of that and they de-condition. They will be performing in a certain baseline performance which is not great, but it's getting them from here to there to do their daily activities.

And then they go through a major insult, in this case a life-threatening bleeding, they de-condition from that level of just getting by or getting along and they are -- they cannot go back to that level. So we call them de-conditioned or debilitated.

That includes generalized weakness, not being able to perform daily functions, sometimes not able to take care of themselves.
Q. Okay. What was your understanding from this record what the cause of the general debility was for Betty Knight?
A. Multiple medical problems compounded by a life-threatening GI bleed.
Q. Did you review the records for Betty's treatment after the GI bleed up until the time she passed?
A. Yes.
Q. And I want to ask you about some of those. Okay?

A. Okay.
Q. If we could turn to Page 37 in the record. We've already looked at it once, but I want to talk to you about a different part of it. Okay?
A. Okay.
Q. This is the record from July 12th, 2013, Dr. Linsenmeyer. Do you see that?
A. Yes.
Q. If you look down under "History of Present Illness," the second full paragraph --
A. Yes.
Q. -- do you see the first sentence? Could you read that to the jury?
A. "She has been weak since all of her recent admissions. She is just not bouncing back. She is having exertional shortness of breath."
Q. Okay. Let me stop you there. The statement she's just not bouncing back, what, what does that mean to you?
MR. LEWIS: Objection, Your Honor, foundation. That's not a medical term.
THE COURT: Sustained.
MR. CHILDERS: I'll withdraw the question, Your Honor.
BY MR. CHILDERS:
Q. Was that a common thing that you saw in these records

saying that she wasn't bouncing back after the bleed?
A. Yes. I believe it was mentioned on more than one occasion.
Q. Okay. Let's look, then, if we could on Page 40. Do you see this is a History and Physical from June 22nd, 2013?
A. Yes.
Q. What's the chief complaint?
A. She is not any better is her chief complaint.
Q. Is that consistent with the record we just saw?
A. Yes.
Q. Okay. And then if we turn Page 43, do you see this is a Discharge Summary from July 22nd, 2013?
A. Page 43?
Q. 43, yes, sir.
A. Yeah.
Q. Do you see that?
A. Yes.
Q. What's the first diagnosis?
A. Generalized debility and disuse myopathy.
Q. Okay. And you told us about debility a few minutes ago; right?
A. Yes.
Q. And then if we go under "Hospital Course," if we could blow that up, could you read for us what the first, the top line says?

A. Under "Hospital Course"?
Q. Yes.
A. "The patient came in because of multiple complaints. She is extremely weak. She is not getting better."
Q. Is that consistent with the two records that we just looked at?
A. Yes.
Q. Then if we turn to Page 45, do you see this is another Discharge Summary from August 17th, 2013?
A. Yes.
Q. And do you see under -- if we could blow up "Hospital Course" again.
Could you read for the jury, what's the first sentence that it says under "Hospital Course"?
A. "The patient was admitted to our skilled nursing unit due to just general debility."
Q. Is that consistent with the records that we have just talked about?
A. Yes, it is.
Q. Is that consistent with the Discharge Summary we saw from where she got out of the skilled nursing after the GI bleed?
A. Yes, it is.
Q. Then if we turn to Page 47, do you see this is a History and Physical from August 22nd, 2013?

A. Yes.
Q. Then if we could blow up "History of Present Illness." Could you just read the first sentence?
A. "The patient is an 84-year-old lady with multiple medical problems recently admitted with chest pain and generalized debility."
Q. And then what it does it say, the rest of that sentence?
A. "Was sent to the skilled nursing unit where she had some rehabilitation."
Q. Okay. And then I want to -- if we could blow up "Past Medical History" that's just underneath there.
A. Uh-huh.
Q. And this is more than two months after she got out of the hospital for the GI bleed; correct?
A. Yes.
Q. Okay. Number 15, could we call that out. What does that say?
A. "History of AV malformation and bleeding."
Q. Is that the bleeding from the May, 2013, hospitalization?
A. Yes.
Q. Then if we could turn to Page 50. Do you see this as a History and Physical from September 1st, 2013?
A. Yes.

Q. And I want to blow up "History of Present Illness." This is the day before she died; right?

A. Yes.

Q. And if we look at the first sentence, it starts out -- it says, "Weak and debilitated 84-year-old white female with a long list of medical problems including," and it has quite a few listed; correct?

A. Yes.

Q. And do you see five sentences down and they include in this AV malformation with bleed of some sort? Do you see that?

A. Yes.

Q. Okay. Did you review Dr. Abdelgaber's testimony in this case?

A. Yes.

Q. Okay. Do you recall his testimony that from the time Betty Knight suffered her GI bleed in May of 2013 that her health declined and never really recovered like he hoped it would? Do you remember him saying that?

A. Yes, I do.

Q. And do you remember him saying that multiple times between the bleed and the time of her death she came back to the hospital and was complaining each time that she just wasn't getting better? Do you recall him saying that?

MR. LEWIS: Objection to leading again, Your

Honor, walking evidence in the record.

THE COURT: Well, it is evidence in the record. Try not to lead.

MR. CHILDERS: Yes, sir. I apologize. I didn't feel like I was leading, but I'll rephrase the question.

BY MR. CHILDERS:

Q. Do you remember Dr. Abdelgaber's testimony --

A. Yes.

Q. -- about what he thought of how Betty Knight did after she had the bleed?

A. Yes.

Q. And the jury has seen that as well.

A. Yes.

Q. Do you agree with Dr. Abdelgaber with what he said about Betty Knight's debility after the bleed up to the time of her death?

A. Yes, I do.

Q. Do you believe that Betty Knight's bleed in May of 2013 contributed to her death in September of that same year?

A. Yes, I do.

Q. Could you explain to the jury why you think that, why you believe that?

A. Okay. So you get somebody, in this case Ms. Knight, with multiple medical problems. She has multi organs that do not function well. And she's just pivoting around the

edge.

And then you hit them with a life-threatening GI bleeding. You think they may not even survive from it. Well, she pulled through, but she never went back to where she was before because it was just too much of a hit on her.

Her hemoglobin dropped down to 6. She wasn't delivering enough oxygen to her vital organs. She became weak and debilitated. They did all that they could for her. They gave her blood. They sent her to rehab. They gave her medication. But she just did not bounce back to where she was before that major hit on the head, the major GI bleed.

It's life-threatening. It's a big hit. Some people even don't make it through the bleed itself. She was lucky to make it for a few months, but it was too big of a hit on somebody with all these risk factors at her age.

Q. And I just want to make sure the jury understands. What's your opinion on whether or not she would have had this GI bleed if she had been on warfarin and had not switched to Pradaxa?

A. I don't think she would have had it as bad. I mean, she's at high risk for bleeding but she was on Coumadin for years and the level was high but she never had the life-threatening bleed. So from that history on that particular patient, I would say "no."

Q. The opinions that you've given us today, have they all

been to a reasonable degree of medical certainty?

A. I believe so.

MR. CHILDERS: That's all the questions I have.

THE COURT: All right. We're going to take about a ten-minute recess before the cross-examination. You may retire to the jury room.

Doctor, you can step down but don't discuss your testimony. Thank you.

(Recess taken at 3:07 p.m.)

(Jury not present.)

THE COURT: All right. Are we ready to proceed? Let's bring the jury out.

(Jury present.)

THE COURT: All right. Be seated.

Mr. Lewis, cross-examination?

MS. JONES: May it please the Court, Members of the Jury.

CROSS-EXAMINATION

BY MR. LEWIS:

Q. Dr. Ashhab, how are you, sir?

A. Good. Thank you.

Q. We've met outside in the hallway, but for the record, my name is John Lewis, and I have some questions for you this afternoon.

Doctor, for your convenience, I've set some of the documents that I may cover with you in front of you. I've also provided a copy to opposing counsel and the Court as well. Let me get a few kind of basics out of the way, if I may, Doctor.

Now, you are a gastroenterologist; is that correct?

A. Correct.

Q. All right. In so being a -- and may I say GI?

Is that a common --

A. Yes.

Q. -- abbreviation?

You probably don't like that.

A. No, it's fine.

Q. But in the context of being gastroenterologist, the GI, you did prescribe medication for some of your patients.

Is that fair to say?

A. Yes.

Q. What you don't do is ever prescribe Pradaxa or anticoagulant medication, correct?

A. Correct.

Q. Okay. But with respect to the medications that you do prescribe, you, before you do so, review the physician label for those medications.

Is that fair?

A. Correct.

Q. And you have a communication with your patient about the risks and benefits of that medication, correct?

A. Yes.

Q. And to the extent those medications come with a patient guide or a Medication Guide, you provide that to your patients, right?

A. Yes.

Q. But you don't leave the room and rely solely on the Medication Guide to provide risk and benefit information to your patients, do you?

A. No. I discuss it with them.
Q. You have a verbal discussion?
A. Yes.
Q. And as far as you know, that is the way doctors do it here in West Virginia, right?
A. Correct.
Q. This state is no different than any other in the United States when it comes to prescription medicines, is it?
A. That's true.
Q. All right. And when patients ask for the physician label -- I don't know how many of yours do, but when they do, you provide it to them, right?
A. Yes.
Q. Do some of your patients ask for the more technical information in the physician label to take a look at it before they take a medication?
A. Some of my patients will ask about resources. We are in the era of the Internet, so I point them to certain websites to get more information about it.
Q. All right. And to educate yourself about a medication before you prescribe it to a patient, you do a little bit of your own research, don't you, sir?
A. Yes.
Q. You not only rely on the physician label, but you may do additional research yourself, correct?

A. Sometimes I do.
Q. A good doctor is going look at literature or maybe talk to colleagues or something along those lines, fully educate yourself about the risks and benefits associated with a medication that you're going to prescribe.
Fair to say?
A. Yes, sir.
Q. All right. And that's what you do in your practice?
A. Yes.
Q. And you think that's a reasonable approach to educating patients about the risks and benefits of a medication?
A. I do.
Q. How many times in your career have you prescribed a medication solely because a patient came in and said they saw a TV ad and did no research on your own?
A. I do not do that usually.
Q. You would never do that, would you, Doctor?
A. I wouldn't.
Q. Right.
So even if a patient came to you and said, hey, I saw a TV ad, you would assess the risks and benefits for that patient independently on your own before prescribing that medication.
Fair to say?
A. Yes.
Q. All right. Let's move to a different subject, and that is

your treatment and diagnosis of what I'll call GI bleeds, gastrointestinal bleeds. Okay? And you talked a little bit about that in your direct examination.

If I recall correctly, you treat maybe a GI bleed once or twice or even more per week, right?

A. Yes.

Q. Okay. Fair to say it's a frequent occurrence in the United States in the patient population to have GI bleeds?

A. Yes.

Q. Okay. Doctors like yourself exist all over the United States treating those complications. Is that fair?

A. Correct.

Q. And you would agree with me that they're more prevalent in the elderly population?

A. Correct.

Q. All right. One type of -- and GI bleeds can occur -- you can have upper GI bleeds, you can have lower GI bleeds. They can occur anywhere in the GI system.

Fair to say?

A. Correct.

Q. In the lower GI system, those are often diagnosed with a colonoscopy; is that fair?

A. Correct.

Q. But you can also diagnose a lower GI bleed without doing a colonoscopy on occasion; is that right?

A. Yes.
Q. Okay. Perhaps a patient is too ill or not well enough to do a colonoscopy, so you have to look at other information or other detail to see if there is a GI bleed; is that right?
A. Yes.
Q. And you've done that on occasion, correct?
A. Sometimes.
Q. You would prefer to do a colonoscopy, is that right, to rule it in or rule it out?
A. Well, it's really more accurate and precise, and it gives you the option to do a therapeutic intervention. So I don't know what you are talking about in terms of other methods, but -- a bleeding scan is a common thing we use sometimes, but it gives you a road map. It doesn't give you exact location.
Q. Right.
Oftentimes during a colonoscopy, you can repair or treat the very source of the bleed or the injury; is that fair?
A. Yes. Correct.
Q. All right. You talked a little bit about AVM, antero --
A. Arteriovenous malformation.
Q. Arteriovenous malformation.
That is something that can occur in patients who are elderly. Is that fair to say?
A. Yes.
Q. Or not elderly; is that right?

A. Less common.
Q. Okay. You've treated folks for AVMs who have not been on anticoagulant medication; is that right?
A. Yes.
Q. Okay. And you've treated folks for AVMs that have been on anticoagulant medication, right?
A. Yes.
Q. And when I say anticoagulant medication, you've treated folks for GI bleeds, including AVMs, who have been on warfarin, right?
A. Yes.
Q. Okay. That can happen, right?
A. Yes.
Q. It's a risk of anticoagulant medication, correct?
A. Yes.
Q. You've treated patients who have been on Xarelto, right?
A. That's true.
Q. And Pradaxa?
A. Yes.
Q. And Plavix?
A. Uh-huh.
Q. Yes?
A. Yes.
Q. And Eliquis?
A. Yes.

Q. All right. Fair to say that no anticoagulant medication exists in the United States today that avoids entirely the risk of a GI bleed?

Is that fair to say?

A. I don't know of any.

Q. You're unaware of any sitting here today.

Okay. Let's talk about the treatment of a diagnosed GI bleed. If you're aware that a patient has a GI bleed, the first thing you want to do is make sure the patient is stable.

Is that fair?

A. Yes.

Q. And by stable, I mean not in a distress and not in a situation where their life is seriously and imminently in danger.

Fair to say?

A. Correct.

Q. Okay. Once that is done, then you start to figure out a plan of how to address the complication; is that correct?

A. Yes.

Q. And that could mean adjusting medication at least temporarily; is that right?

A. Yes.

Q. For someone on an anticoagulant medication, any of them -- Xarelto, Eliquis, Pradaxa, warfarin -- you might stop the medication for a temporary period of time?

A. Yes.
Q. And that allows you to better treat the complication; is that fair?
A. Yes.
Q. All right. That's very common; is that right?
A. Yes.
Q. The next thing you may want to do, and probably do, is to identify the source of the injury or the complication; is that right?
A. Yes.
Q. And in the source of -- in the instance of an AVM, you want to identify where the AVM is and determine whether something can be done to repair or treat it.
Fair to say?
A. Yes.
Q. All right. And you would agree with me that, generally speaking, complications in the lower GI tract like AVMs are typically resolved within about a day, most of them?
A. If you do intervention, you mean? If you clip them or burn them?
Q. Correct.
A. Yes.
Q. They're treated.
A. They are treated, yes.
Q. So if they're identified and treated, generally speaking,

most of them are done or treated within about a day. That would be a successful treatment of an AVM or a GI bleed.

Is that fair?

A. Yes.

Q. Okay. So just so I'm clear, if you have a patient, and they present with a GI bleed that you suspect is an AVM, you would deem it to be a successful intervention or a successful treatment if you can repair that complication within about a day; is that fair?

A. Yes.

Q. And that is about 90 percent of the folks that you treat, you do repair or treat successfully within about a day?

A. If we are able to identify the source, yes.

Q. And that is true for anybody who is on any kind of anticoagulant medication, right?

That would still be a successful treatment if you could get after that complication and get it repaired within a day; is that right?

A. Yes.

Q. Okay. Let's about talk about Mrs. Knight for a couple of minutes.

Now you've had a chance, as part of your work in this case, to review a lot of medical records related to Mrs. Knight; is that fair?

A. Yes.

Q. And you feel like you've reviewed all of the records that you need to review to form your opinions?
A. I believe so.
Q. And you've seen the medical histories dating back in time maybe six, seven, maybe more years; is that fair?
A. Yes.
Q. All right. And you've read the home health care records and the doctors' notes and the reports from office visits, things like that; is that right?
A. Yes.
Q. You would agree that Mrs. Knight, at the time that she first went on an anticoagulant medication, which was warfarin, she needed it?
Fair to say?
A. Yes.
Q. Okay.
MR. LEWIS: And if we could get the opening slide related to the risk factors.
Q. You actually -- as part of your work in this case, you did look at Mrs. Knight's circumstances -- and I have on the screen to your left some of the risk factors.
But you independently looked to see whether Mrs. Knight did have a high risk of suffering from stroke based on her circumstances at the time that she took warfarin; is that right?

A. Yes.
Q. Okay. And she did, right?
A. Yes.
Q. All of these factors -- the age, the fact that she's a female unfortunately, a prior stroke that she had, hypertension, vascular disease, diabetes, congestive heart failure that she was experiencing -- those things increased Mrs. Knight's risk of a stroke at the time that she began anticoagulant medication; is that right?
A. Yes.
Q. And you would agree with me that these risk factors only got worse with time?
A. Yes.
There is, however, a discrepancy in the record towards congestive heart failure because it was not consistent in the mention. The other factors were all the time consistent. I just want to point that out.
Q. Okay. Periodic congestive heart failure, is that fair to characterize it that way?
A. Maybe.
Q. Okay. There were lots of instances in the record where Mrs. Knight had experienced heart failure symptoms; is that right?
A. That's true.
Q. Okay. She had a history of heart attacks?

A. Yes.
Q. And there's no question in your mind that she was an appropriate patient for anticoagulant medication.
Fair to say?
A. Yes.
Q. Okay.
MR. LEWIS: Finished with that slide. Thank you.
Q. Now, you know that in 2005, Mrs. Knight began to take warfarin or coumadin as a medication, an anticoagulant medication, right?
A. Yes.
Q. All right. You reviewed medical records beginning in 2007; is that right?
A. Around that time, yes.
Q. All right. And there were a handful of physicians that prescribed warfarin and treated Mrs. Knight between 2005 and 2007; is that right?
A. Yes.
Q. Those are records that you haven't reviewed, correct?
A. I did not review all those, no.
Q. So sitting here today, we don't know -- based on the records, the medical records that were made available to you, we don't know how she did on warfarin when she first took it for the first two years; is that right?
A. I believe the records I have start around 2008 --

Q. Okay.
A. -- on through 2013.
Q. Okay. So 2005, '06 and '07, those are just records that you didn't have an opportunity to review?
A. That's correct.
Q. Did you want to see those, if they were available?
A. I'm not sure how relevant they would be.
Q. Would you want to have known if Mrs. Knight had experienced a prior bleed on warfarin in that time frame?
A. Yeah. That would be important information.
Q. Would you want to have known if Mrs. Knight had experienced stroke during that time frame?
A. They mention in the record that she had a previous history of stroke, so we knew it happened before 2008.
Q. Okay.
A. That's in the record.
Q. When Mrs. Knight started on warfarin in 2005, she was at less risk of a stroke than she was later on in her life.
Is that fair to say?
A. Because she got older.
Q. And many of the things that caused her to have high stroke risk in 2005 continued to get worse over time; is that right?
A. Yes, sir.
Q. So that risk became increased?
A. Yes.

Q. Fair to say?

Now in 2005, when Mrs. Knight went on warfarin, there was really one choice for anticoagulant medication, right, warfarin?

A. Yes.

Q. All right. Pradaxa wasn't on the market until 2010, right?

A. Yes.

Q. And these other medications, such as Xarelto and Eliquis, weren't available until later either, correct?

A. Yes.

Q. All right. And warfarin at the time was really the number one and really the only medication to treat folks who had AFib, atrial fibrillation -- the jury has heard AFib -- with a significant stroke risk?

A. Yes.

Q. The thing about warfarin, though, is it did come with some risks, right?

A. Yes.

Q. One of the risks is if you thin the blood, you can obviously have bleeding events, right?

A. Yes.

Q. Warfarin has that same risk, and it's a significant risk, right?

A. Yes.

Q. Okay. The other thing about warfarin is, is it's kind of tough to keep it within the therapeutic range.

Fair to say?

A. Yes.

Q. There's a therapeutic range with warfarin, and it's measured by looking at INR levels. INR, the jury has heard that.

A. Yes.

Q. You're familiar with that?

A. Yes.

Q. And I think that is International Normalized Ratio is what that stands for, right?

A. Correct.

Q. All right. And the key is you want to keep that therapeutic range, you want to keep the INR levels with a patient generally between 2 and 3; is that right?

A. Yes.

Q. And if you go below 2, you're going to increase the risk of stroke; is that right?

A. Yes.

Q. And if you go above 3, then you're going to increase the risk of a bleeding event to occur; is that right?

A. Yes.

Q. So it's really, really important to keep those INR levels between 2 and 3; is that right?

A. Yes.
Q. And that can be a problem for folks as they get older to keep the range between 2 and 3; is that right?
A. Yes.
Q. Gotta be very careful with your diet, correct?
A. Yes.
Q. Gotta be very careful with what other medications you're taking, correct?
A. Yes.
Q. You gotta be careful with what you eat, right?
A. Yes.
Q. And you gotta make sure that you go to the doctor on a regular basis and that you get to the physician's office to have those blood levels monitored, correct?
A. Correct.
Q. And all of those things need to happen in order to maintain that therapeutic range with warfarin, right?
A. Yes.
But doctors have also designed and came up with a warfarin clinic. So some of these challenges are really managed through a designed clinic that provides information about diet and look at medication interaction and make sure the patients get their blood tested on time or send a nurse or a home health care to do their blood. So it's not always the patient has to actually come to the doctor to have it done. There are

other ways to make life easier to monitor their INR.

Q. But, Doctor --

A. But it has to be monitored, you're right.

Q. Okay. Thank you.

If you could answer my question, I promise I'll get you out of here today. If you don't, I can't promise you anything. Okay?

All right. Fair enough, though.

A. It's not a threat. It's a promise, not a threat.

Q. That's right, only promises.

A. All right.

Q. All right. But let's be fair, there are some physicians who have made it a little bit easier to get blood tested when they have a patient on warfarin than others.

Fair to say?

A. Yes.

Q. They've sort of designed their office around helping patients make it a little easier because it's really, really important to keep the blood within that therapeutic range, right?

A. Yes.

Q. That's why doctors have set up these special circumstances and situations to make it easier for patients, right?

A. I meant to say there is a warfarin clinic that doesn't belong to any certain doctor.

Q. Sure.
A. We can refer them to the warfarin clinic to help them.
Q. Right.
A. That's what I meant.
Q. Right.
There are clinics that have been set up to make it easier for patients, right?
A. Yes.
Q. Because it's so important to keep those levels between 2 and 3, right?
A. Yes.
Q. Because the last thing we want are patients who are outside of that 2 and 3 because then the risks increase, correct?
A. Yes.
Q. All right. Fair enough.
Now, have you reviewed the label for warfarin? I assume you have --
A. Yes.
Q. -- when you treat patients.
A. Yes.
MR. LEWIS: It's Exhibit 5861, the very first one in your binder.
At this time, Your Honor, I'll move for the admission of 5861, Defendant's 5861 into evidence.

THE COURT: Any objection?

MR. CHILDERS: No, Your Honor.

THE COURT: It's admitted. It may be published.

(DEFENDANT'S EXHIBIT 5861 ADMITTED INTO EVIDENCE.)

MR. LEWIS: Let's take a look at the first page, Doctor.

Q. These labels for medicines look similar, they're designed similarly.

Is that fair to say?

A. Yes.

Q. One of the things that you see is up in the upper left-hand corner, there is a lot of important information usually in that spot, right?

A. Yes.

Q. In the warfarin label from 2011, we see that down in the bottom right-hand corner. No question about it, coumadin or warfarin -- that's the same, it's the same medicine, right?

A. Yes.

Q. Can cause major or fatal bleeding, correct?

A. Yes.

Q. Perform regular monitoring, that's what we talked about, correct?

A. Yes.

Q. Drugs and dietary changes can affect INR levels. That's important, we talked about that, right?

A. Yes.
Q. And then obviously instruct patients to minimize the risk of bleeding and to report signs. That's in a box in the upper left-hand corner. That means it's really, really important information; is that right?
A. Correct.
Q. All right. And if we look at the right-hand side, Adverse Reactions, most common adverse reactions to coumadin are fatal and non-fatal hemorrhage from any tissue or organ.
That's a bleed, right?
A. Yes.
Q. Then you can have with warfarin life-threatening bleeds just like you described, correct, where there is several pints of blood that have to be transfused, right?
A. Yes.
Q. That can happen on warfarin, right?
A. Usually not in the therapeutic range. When somebody is over-anticoagulated, it may happen.
Q. Somebody who is outside of the range --
A. Yes.
Q. -- is more likely to get a very, very serious life-threatening bleed.
Fair to say?
A. That's correct.
Q. Probably in the range of about 3, not below. But you're

probably more likely to get a life-threatening bleed if you're outside and higher than that INR level of 3; is that right?

A. Usually more than 5 or even 10.

Q. Okay. And you agree with me that the most serious risk for patients who are on warfarin is a bleed risk when their INR levels are outside of the range, right?

A. Yes.

Q. Okay. Now, there's also a section called Contraindications, and that is going to be on page -- it's going to start on page 5861-009. There are numbers at the bottom of the page.

A. Okay.

Q. And if we go to the next page, 010, these are contraindications, and the fifth bullet point down: Unsupervised patients with conditions associated with potential high level of noncompliance.

You know what that means, don't you, Doctor?

A. Where was that again?

Q. Sure. That is --

A. Page 10?

Q. -- on page 5861-010, fifth bullet point down, right after the --

A. Yes. Unsupervised with conditions associated with potential high level of noncompliance. Yes, I found it.

Q. Right.

And noncompliance is patients who don't take their medication on a regular basis or perhaps forget it, right? That could be noncompliance, correct?

A. Yes.

Q. Or patients who aren't able to or won't go to the doctor and have -- or a clinic and have their blood tested on a regular basis, correct?

A. Correct.

Q. Because patients who make it difficult to monitor the INR levels are patients who are at a higher risk of bleed or stroke, right?

A. Yes.

Q. And in fact, these patients are contraindicated by the label. Is that fair to say?

A. Yes.

Q. Okay. And that would include patients who may be suffering from dementia and are having trouble remembering whether they took their medication as well, correct?

A. Yeah. If they have no care provider to give it to them, yes.

Q. And we know also later in the label, pages 14 and 15, discuss the various interactions.

You're aware, Doctor, that there are many, many drug interactions that affect warfarin in a patient, right?

A. Yes.

Q. And if we look at the CYP450 interactions -- do you know what that means?

A. Yes. That is a measure, cytochrome p450 in the liver. That is responsible for a whole type of metabolism of medications. I cannot name how many there are. Almost everybody goes through cytochrome p450. So --

Q. All right. Most medications are metabolized through the liver, or many of them, right?

A. Yes.

Q. And warfarin is one of those medications?

A. Yes.

Q. And if you have another medication that is metabolized through the liver that you're taking, it can really affect your warfarin absorption, correct?

A. Yeah, if they are inducers or inhibitors. So some potentiate the effect, and some inhibit the effect.

Depends on the action of --

Q. It depends. One could do one thing, and one could do another, right?

A. That's true.

Q. And if you look at the next page, we have examples of these inhibitors, right, that --

A. Yes.

Q. -- you have to watch?

And there's a whole laundry list of those potential

medications that can affect warfarin levels, right?

A. That's true.

Q. So if you have a patient that is on a lot of other medications, that can be a real problem to manage that patient's warfarin, correct?

A. Yes.

Q. All right. And I think we already discussed the fact that foods can affect it, too. A lot of leafy greens and foods with vitamin K can affect the warfarin interaction; is that right?

A. Yes.

Q. If we look at the page -- and I'll just go to page 5861-31, you see that warfarin also comes with a Medication Guide just like Pradaxa. Just like all anticoagulant medications, there's a Medication Guide, and so I want to ask you a couple of questions about that.

First of all, you agree with me that a Medication Guide shouldn't have all of the technical information that a physician label has, correct?

A. Yeah.

Q. These are made for patients, right? And it needs to be more simpler language so the common person can understand it, right?

A. Yes.

Q. All right. And you see here, what is the most important

information I should know about coumadin, can cause bleeding which can be serious and sometimes lead to death.

MR. CHILDERS: Judge, could we have a side bar?

THE COURT: Yes.

(Bench conference, reported.)

MR. CHILDERS: Your Honor, I didn't ask any questions about the Medication Guide. I --

THE COURT: With respect to coumadin?

MR. CHILDERS: With respect to either. I only asked about the physician label, not the Medication Guide. So Mr. Lewis is outside the scope.

MS. JONES: I mean, the theory in the case is that your Medication Guide was deficient. I don't know how you can separate one from the other. I mean, they are basically saying we didn't warn patients about the risks associated with this particular drug. I mean, that's the heart of the case.

THE COURT: But this is not the expert who is supplying that. Certainly not with respect to the Medication Guide that refers to Pradaxa, but nothing like this was in his examination of the doctor pertaining to warfarin or coumadin.

MR. LEWIS: Well, the testimony was that if she were on warfarin, she would have been okay. And because she wasn't, she wasn't okay. She was on Pradaxa.

So I'm showing two things with the Medication Guide. Number one is that the information we supplied to

physicians -- and by the way, the Medication Guide is provided to physicians, the Medication Guide is also provided to physicians, so this is within the realm of something that a physician would review. So that's number one.

Number two is it also goes to causation, that warfarin has the same risks associated with it as Pradaxa does.

MR. CHILDERS: I didn't object to that from the label because I asked him about the physicians label. Dr. Plunkett talked about the Medication Guide. That would have been the witness to ask these questions to. He's not testified at all about the Medication Guide. All he has talked about is the physician label.

THE COURT: But he's also testified doctors receive the Medication Guides and consult them as well, so I'm going to allow it.

MR. CHILDERS: I didn't ask him that.

THE COURT: That's what I'm saying.

Your witness has testified --

MR. CHILDERS: I understand. Okay.

Thank you, Your Honor.

(Bench conference, concluded.)

MR. LEWIS: Just to pick up where I left off, the Medication Guide for warfarin or coumadin says: Coumadin can cause bleeding which can be serious and sometimes lead to death.

Q. And that's right there for patients to see, right, Doctor?
A. Yes.
Q. All right. And if we scroll a little bit further down, we see you may have a higher risk of bleeding if you take coumadin and -- and there is a whole laundry list of other things. Just like Pradaxa has some things that increase the risk of bleeding, coumadin has the same thing, correct?
A. Yes.
THE COURT: Pull that microphone down just a little bit.
THE WITNESS: Yes. But be careful with this data because it plays against some of the stuff you started with.
So, for example, No. 4 says history of stroke. But you, just in your introduction, told me we give the blood thinner to prevent stroke. So if this wording was correct, then she wouldn't get coumadin or any blood thinner, but that's not the truth.
See, there's a difference in practice when you have a patient to treat between what is in the paper and what is in the trials and what are the risks for that particular patient.
MR. LEWIS: Wholly agree with you, Doctor. I want to ask you about that.
Q. So you would agree with me that sometimes a doctor has got to put this label aside and treat a patient, that particular patient in front of him or her.

Fair to say?

A. I wouldn't say put it aside. I would say take it into consideration. But then, on top of that, add special circumstances for that particular patient that make them maybe not a candidate for that medication, only actual testing for that medication.

Q. But each one of those inquiries is specific to a particular patient that is sitting in front of that doctor, right?

A. Exactly.

Q. Right.

And as a physician, the Medication Guide and the physician label is informative, correct?

A. Yes.

Q. But you also use your experience, correct?

A. Yes.

Q. And you also use your assessment of that patient, correct?

A. Yes.

Q. And you have to make a risk-benefit decision for that patient on what the best medication is, right?

A. Correct.

Q. And you know that in your practice -- in your practice, you don't actually make those risk-benefit decisions when it comes to anticoagulant medication, correct?

A. Usually the patient comes to me with a problem that

happened, and they have already been on the medication. However, I do recommend based on my findings, with the measurement of the bleeding, recommendations towards whether the patient should discontinue this medicine or the other, and discuss it with the prescribing doctor.

Q. Fair enough.

Just to close out this Medication Guide, the one thing I wanted to cover was that last bullet point that says: You may have a higher risk of bleeding if you take coumadin or warfarin -- sodium, that's the active ingredient, right, Doctor?

A. Yes.

Q. If you take it for a long time, right?

A. Yes.

Q. The longer you're on warfarin, the higher the risk you have of a bleed, right? That's what it is saying right there.

A. Yes.

Q. And that is true, right?

A. Yes.

Q. You know that?

A. Yes.

Q. Okay.

MR. LEWIS: I am finished with that. Thank you.

Now, you talked a little bit about Mrs. Knight's experience on warfarin. And as I recall you testifying, you

indicated that she probably would not have had a bleed if she were on warfarin in 2013 instead of Pradaxa.

Q. Did I get that right?

A. Close, but not quite.

Q. Okay.

A. I said wouldn't have had a life-threatening bleed --

Q. Okay.

A. -- compared with Pradaxa.

Q. Okay. So your testimony is that she may have -- she was probably just as likely to have had a bleed with warfarin as she was -- as she did with Pradaxa, the risk was the same?

A. No, not as likely. It is more likely to bleed on Pradaxa as compared with coumadin from the gastrointestinal tract.

Q. So what I wanted to ask you about is, you also said she had -- she was well managed on warfarin? Is that what you had indicated?

A. I don't think that came up in the discussion. I said she was managed on coumadin with monitoring INR.

Q. Understood.

So do you believe, is it your opinion that she was managed successfully while she was on warfarin or coumadin?

A. To the best of my recollection of the record, that she had sometimes INRs that were above the desired range. But I do not recall that she ever had a gastrointestinal bleed on coumadin. For sure, she did not have any life-threatening

bleeding on coumadin for that time that I viewed.

Q. But you agree that when the INR levels are out of the therapeutic ranges, there is a significant risk of bleed if they are significantly above 3?

A. I said significant bleed usually we see above 5 and 10, not just above 3. Because there are some people whose therapeutic range is really up to 3 and a half, for example, and that is their desired range. So I usually, in my over 20 years of experience, do not see GI bleeds with an INR of 2 and a half, 3, 3 and a half or even close to 4. Very, very rarely. The ones I see are usually INR way high above 5 and above 10.

MR. LEWIS: All right. Well, let's go to an opening slide on the INR levels. This was shown in opening by Ms. Jones.

Q. And you looked at all of the medical records associated with the INR readings for Mrs. Knight, right?

A. The ones that were provided to me --

Q. Right.

A. -- I did.

Q. And there were a lot of INR readings, correct?

A. Several ones, yes.

MR. LEWIS: Your Honor, we've prepared a summary of the INR levels that has been marked as Defendant's Exhibit 9009S. It's a Rule 1006 summary. I would move for the

admission of that summary at this time.

THE COURT: Any objection?

MR. CHILDERS: I'm going to object to the admission as an exhibit. If it's a demonstrative, that's fine, but I don't believe this has been authenticated, a foundation hasn't been laid for it. So --

THE COURT: So is it a demonstrative exhibit?

MR. LEWIS: This is a demonstrative. I have a summary that is not a demonstrative that is being moved into evidence that I've provided to Mr. Childers.

THE COURT: And this chart purports to represent the document you just referred to that is the summary of all of her INR reports?

MR. LEWIS: Correct. And we've made the documents available to Mr. Childers. In fact, I provided those to opposing counsel this morning as back-up, but they were medical records that were already exchanged.

THE COURT: All right. On that representation, I'll allow you to use them.

MR. LEWIS: So could we pull up 9009S.

All right. So this is a very generic chart that is in front of you. And this is just charts in the medical records as 9009S, charts in the medical records, the INR readings from the various medical records over time.

And if we just scroll down, you can see that there

is -- the numbers change over time. There's a date, the numbers are in the middle. You can see that.

And you can see that there is --

THE WITNESS: Do I have that in here? Do I have this here?

MR. LEWIS: You have it in front of you. It is towards the back of your binder, and it would be 9009S.

THE WITNESS: Okay.

BY MR. LEWIS:

Q. You reviewed the INR levels for Mrs. Knight, though, as part of your work in this case, right?

A. Yes.

Q. And so you know that she spent more time out of therapeutic range than in therapeutic -- in therapeutic range, right?

Did you ever count them up?

A. I didn't really count them up. I looked at them, but I didn't count them one by one.

MR. LEWIS: Well, the demonstrative plots these numbers, so let's go to that.

Q. And you can see here that the therapeutic range in the demonstrative that is in front of us shows the range 2 to 3, and the yellow is the therapeutic range. And anytime there's a white dot, that is outside the therapeutic range, right?

A. Yes.

Q. And you see that at least on a couple of occasions she had INR levels as high as 8.

That's a serious risk of bleed right there, right?

A. Yes.

Q. And other levels that approach 6 and were above 6 in other instances, right?

A. Yes.

Q. And then several levels below 2. That means that she is at a higher risk of stroke because she's not within the right level; is that correct?

A. Yes.

Q. All right. And you see that over time there was consistent out-of-range readings on the INR levels. If you just look at the time frame, it's consistent, right, just like Dr. MacFarland said?

A. Yes.

MR. LEWIS: And let's take a look at Mrs. Knight's circumstances on warfarin in 2008. And if we could -- I am finished with that exhibit.

I'm going to move for the admission of Exhibit 9003A, which is a sub-exhibit of the medical records similar to what the plaintiffs have done here.

MR. CHILDERS: No objection, Your Honor.

THE COURT: It's admitted.

(DEFENDANT'S EXHIBIT 9003A ADMITTED INTO EVIDENCE.)

MR. LEWIS: If we look at 9003A. Sorry. Exhibit 9003A.

THE WITNESS: 9003, you said?

MR. LEWIS: Yes.

THE COURT: 3A.

THE WITNESS: Thank you, Your Honor.

Yes, sir.

MR. LEWIS: Are you able to -- do you have that?

THE WITNESS: I have, yeah, 9003A.

MR. LEWIS: All right. Just to orient ourselves, so Mrs. Knight -- this is a record from the 2008 time frame that's in front of you. And --

THE COURT: The first page of it is the certification.

MR. LEWIS: Sorry. The second page of 9003A. You have a certification that shows it was --

THE WITNESS: Yes.

MR. LEWIS: -- authenticated, and now we have the record itself.

THE COURT: It's page 10 in this sequence at the bottom?

MR. LEWIS: Correct.

THE WITNESS: This chart summary?

MR. LEWIS: Ten at the bottom, 9003-10.

THE WITNESS: Yes.

MR. LEWIS: Okay. Go to the second page.

And we see up in the top, this is -- date admitted was August 7th of 2008.

Q. This is a Dr. MacFarland record; is that right?

A. Yes.

Q. And we have here Mrs. Knight coming to see Dr. MacFarland for a number of things, but really acute respiratory failure.

If you look at the brief history and hospital course shortly down, you see that she's had a number of issues. But she's coming to see Dr. MacFarland because, in the fourth line down, she called and went to the emergency room with acute respiratory failure and then eventually wanted to come to see Dr. MacFarland, right?

A. Yes.

Q. And if we fast-forward to two thousand -- excuse me -- 9003-12, you see under diet, as tolerated?

A. Yes.

MR. LEWIS: Are you able to scroll through the next -- the same day, it's just two pages -- there you go, she is currently off.

Q. You see Dr. MacFarland is noting that Mrs. Knight is off coumadin, off warfarin at this time in 2008?

A. Yes.

Q. She's going to try something else. And Dr. MacFarland is explaining to her that coumadin is the gold standard, but at this time Mrs. Knight doesn't want to come to the office to

get the blood work checked as frequently, right?

A. Yes.

Q. She's declining it at that point in time.

Is that fair to say?

A. That's what she said, yes.

Q. Okay. But if we fast-forward one month --

MR. LEWIS: And this is going to be Exhibit 9007, and I move for the admission of 9007A. Those are medical records.

MR. CHILDERS: No objection, Your Honor.

THE COURT: They're admitted.

(DEFENDANT'S EXHIBIT 9007A ADMITTED INTO EVIDENCE.)

MR. LEWIS: 9007A, pages 8 and 9.

THE WITNESS: Yes.

MR. LEWIS: So we see this is a visit with Dr. Haberman from a month later, September 18th, 2008.

And if you look at the bottom impression, she has a history of stroke. And Dr. Haberman is saying Mrs. Knight absolutely needs to get back on her coumadin because her risk having another stroke, another stroke, is high.

Now, if we look at the next page on -- look at No. 3. This is what Dr. Haberman did. She was on Plavix. Took her off Plavix and said discontinue Plavix to prevent bleeding from the concomitant --

Q. That means at the same time, right, Doctor?

A. Yes.

Q. -- aspirin and coumadin therapy.

Dr. Haberman, right, Doctor, is expressing a concern about putting this particular patient on Plavix and warfarin at the same time.

Is that fair to say?

A. Yeah. The more blood thinners you have, the higher the risk of bleed.

Q. Right.

And that is something that Dr. Haberman is concerned about as early as 2008, right?

A. Yes.

Q. So that --

A. But also I'm not sure what is the indication here for Plavix. It was given because she did not want to take the coumadin. But now that she agrees to the coumadin, she doesn't need the Plavix. I'm not sure that he needs to stop it. She doesn't need it.

Q. If you read No. 3, it says: Discontinue Plavix to prevent bleeding from concomitant aspirin and coumadin therapy, right?

A. Yeah, I see what you're saying.

Q. Right.

He considered triple therapy and said no, right?

A. Yes.

Q. Okay. If we go later into 2008, we talked a little bit about whether or not she had a bleed. And it's your opinion

that she didn't experience a bleed after she went back onto coumadin at this time; is that right?

A. I saw no evidence of that in the chart.

Q. Okay. Well, if we go to 9007-19 --

A. Dash 19.

Q. -- we just see here that this is Mrs. Knight coming in to see Dr. MacFarland and to discuss some mental status changes.

She's experiencing some weakness, right?

A. Yes. Yes.

Q. Okay. And at this point in time, she's also -- her family is concerned about -- if you see in the history of present illness, is concerned about a little bit of her potentially progressing dementia at the time; is that right?

A. Yes.

Q. Okay. And there was some concern about that.

If we go to 9007-36 and -37 during the same time frame -- if we go to 9007-36, we see that eventually Mrs. Knight works her way to Dr. Haberman again.

A. Yes.

Q. And he notes here on the front page -- and this is right around the same time frame, mid November 2008. She's on coumadin.

And if we go to page 37, the very next page, Dr. Haberman down in impression, in recommendations says: She is experiencing anemia, which might be secondary to the recent

initiation of coumadin, right?

A. That's what it says.

Q. He's saying that she might be experiencing a bleed because of the recent initiation of coumadin, correct?

A. That's what it says, yes.

Q. That's what he is suspecting here in November of 2008, right?

A. Yes. He's suspected that, yes.

Q. Right. Sure.

And the very first thing he says in his recommendations is stop coumadin, right?

A. That's what it says, yes.

Q. Okay. And if we flip back into 9007-25, we see this is a consult right around the same time frame, in mid November, with Dr. Rohrbach.

Do you see that on the right-hand side?

A. Yes.

Q. Now you know Dr. Rohrbach is a GI specialist here in Huntington, right?

A. Yes.

Q. Okay. And Dr. Rohrbach says in the history: She has been seen by Dr. Haberman, and she was found to be anemic.

Do you see where it says that in the middle of history?

A. Yes.

Q. In the emergency room, her hemoglobin was 10. By

yesterday it was down to 9.

It's dropping, correct, Doctor?

A. Yes.

Q. Okay. She's been transfused two units.

Do you see where it says that?

A. Yes.

Q. That suggests a blood loss, right, Doctor?

A. Well, she has more than one reason to be anemic, but it did drop from 10 to 9.

Q. And she is transfused with two units of blood, right?

A. Yes. Yes.

Q. That suggests she's losing blood, correct?

A. Not always. I hate to get into this, but people can have hemolysis or can have lack of production or can have bleeding. But the problem here is nobody documents that they have seen any blood or tested for any blood.

Q. Understood.

A. So I don't see a GI bleed here. He's implicating or he's guessing, but there really -- there is no documentation that she has GI bleeding --

Q. Understood.

A. -- and that's the problem.

Q. Understood.

But the GI specialist is being consulted here, correct?

A. Correct.

Q. And he's noting that she is -- her hemoglobin is dropping, and she's been transfused two units, correct?

A. Correct.

Q. And then he goes on to say she's had some darker stool, which is indicative of a potential GI bleed, correct, Doctor?

A. Correct.

Q. Okay. This GI specialist is suspicious of a GI bleed, correct?

Now you know from the records that eventually a colonoscopy wasn't done because they felt Mrs. Knight was too ill. You know that, right?

A. That's what it says in the records.

Q. Right. Okay.

But when we look at what the doctor said later in the documents that weren't shown to you on direct examination, we see that they do refer to a GI bleed, right? You know that, right?

A. They mention it in the notes.

Q. Right. So --

A. But there's no documentation of it.

Q. Okay.

MR. LEWIS: Let's take a look at the documentation in Exhibit 9009, which I'll move for admission of at this time.

THE COURT: Any objection?

MR. CHILDERS: No, Your Honor.

THE COURT: It's admitted.

(DEFENDANT'S EXHIBIT 9009 ADMITTED INTO EVIDENCE.)

MR. LEWIS: If we go on to 9009A, and we go to page 273 and 275 -- we'll just go to 273.

Q. We see this is Dr. Gunnalaugsson from December of 2008, and you see that in the history of present illness, Dr. Gunnalaugsson is talking about doing a stent procedure, correct?

A. Yes.

Q. And he's choosing a bare metal stent, correct?

A. Yes.

Q. And a bare metal stent is chosen if a doctor is worried about extensive bleeding because you have to go on less anticoagulant medication with a bare metal stent.

Fair to say?

A. Less blood thinners, yes.

Q. Yes.

And if we go to what Dr. Gunnalaugsson says on page 275 under Assessment and Plan, you see right in the middle: She has been on coumadin for atrial fibrillation, but this was stopped because of her chronic bleed.

You see where it says that?

A. Yes.

Q. And then instead, she's on aspirin and Plavix, and they took her off coumadin, right?

A. I see that, yes.

Q. Okay. And this is right in the records. This is in writing, right?

A. Yes, I see it.

Q. Okay. If we look back at 9007, we see what happens because she wasn't on coumadin.

On 9007-55, we see this is Dr. Linsenmeyer for Mrs. Knight in February of 2009. Again, Dr. Linsenmeyer is consulting with Dr. Gunnalaugsson. Mrs. Knight is not on coumadin at this point. Dr. Gunnalaugsson thinks it's because of prior bleed.

And we say: For the last five days prior to presentation, the patient noticed that her fingerprints were turning discolored. She began to experience severe right brachial arm pain.

She has a blood clot here, right, Doctor?

A. Yes.

Q. She suffers from a blood clot in February of 2009, right?

A. Yes.

Q. Okay. And this is the constant problem that the physicians were facing with Mrs. Knight during the entire course on warfarin, right? This was a problem for them, wasn't it?

A. After they stop it, they got a clot. If they don't stop it, they have a hard time monitoring it.

Q. Right.
A. Yeah, it was a challenge. It was a big challenge, yeah.
Q. They were having trouble keeping Mrs. Knight on warfarin within the therapeutic range.
Fair to say?
A. Fair to say.
Q. And we just saw an example where, because her INR levels were too high, she suffered from a suspected bleed, correct?
A. Correct.
Q. And when they try to take her off the warfarin to try to bring the INR levels down, she suffers a clot, right?
A. Correct.
Q. That's not a well managed warfarin patient, is it, Doctor?
A. She seems to have problems either way.
Q. Yeah.
Difficult, right?
A. Difficult, yes.
Q. Very difficult.
A. A challenging patient.
Q. And some patients are like that, correct?
A. Correct.
Q. Some patients like Mrs. Knight are very, very difficult to manage on any medication, including warfarin, right?
A. Correct.
Q. On the one hand, you are darned if you do, and you are

darned if you don't, right?

A. Yes.

Q. And that's what is going on here in 2009 with Mrs. Knight, right?

A. Correct.

Q. It gets worse by 2011, doesn't it, Doctor?

A. Yes.

MR. LEWIS: In fact, let's go to Exhibit 9009-389.

THE COURT: 9009A?

MR. LEWIS: Sorry. 9009A-389. Sorry, Your Honor.

Let's look at the last seven days Mrs. Knight was on warfarin. Day one, October 10, 2011, Dr. MacFarland gets a call. Mrs. Knight's INR levels are at 8 again.

Q. You see that on the message, 9009-389?

A. Oh, 389.

Q. Sorry.

A. Yes.

Q. INR of 8; you see that?

A. Yes. Yes.

Q. That is serious, right?

A. Yes.

Q. Here she is at a bleed risk again, correct?

A. Yes.

Q. Dr. MacFarland says go to the ER, right?

A. Yes.

Q. And you see a note here that the wait maybe at the ER was too long or was called in, and she couldn't get her in. So call in vitamin K.

That's the antidote, right?

A. Yes.

Q. All right. And then if we go to 9009-385, two days later, her INR is 5.

That is still high, right, Doctor?

A. Yes.

Q. Dr. MacFarland is saying hold the coumadin tonight, don't take it, recheck the INR tomorrow, correct?

A. Yes.

Q. If we go to 9009-383, a day later, her INR is back up to 6.3.

That's a high risk of bleed still, right?

A. Yes.

Q. So now we're on day three of high risk of bleeding for Mrs. Knight in October of 2011, correct?

A. Yes.

Q. All right. If we go to 9009-448, we see in the middle the INR reading is now down to 4.6.

Do you see that?

A. Yes.

Q. It's getting better, it's improving, correct?

A. Yes.

Q. The doctor says take vitamin K, and we're going to recheck the INR, correct?

A. Yes.

Q. If we go to 9009-425, it is a handwritten note, kind of hard to read.

A. Oh, yes.

Q. But if we look at the data reviewed towards the bottom of 425, we see now that they've overshot this. Now the INR is at 1.6.

A. Yes.

Q. Data reviewed, the INR is now at 1.6.

Now she's back on the high risk of stroke, right?

A. Yes.

Q. During this entire time, none of these readings are within the therapeutic range, correct?

A. Yes. That's why you send these people to the warfarin clinic.

Q. The doctors are struggling to keep Mrs. Knight in the therapeutic range, right, Doctor?

A. Yes.

Q. And look at what is said in the upper left-hand corner of this document: Want to replace coumadin. New medication, Pradaxa.

There's nothing about a TV ad in here, is there?

A. I don't see it here.

Q. What's going on here when the switch is made from coumadin to Pradaxa is that the doctors were struggling to keep her safe on warfarin, right?

A. That's what this record says.

Q. Okay. And let's look at what Dr. MacFarland herself said on 9009-580.

A. Dash five --

Q. Dash 580, 9009A-580.

A. Got it.

Q. You know, sometimes you probably have done this, you had to fill out forms to justify medications?

A. Yes, sir.

Q. And when you do that, it's important to tell the truth and be honest and accurate about that; is that right?

A. Yes, sir.

Q. Okay. And Dr. MacFarland is filling out this form on October 18th of 2011, after these seven or eight days of never having Mrs. Knight within a safe range to use warfarin, right?

A. Yes.

Q. And the diagnosis is: Sporadic and supratherapeutic on coumadin. Do you see that?

A. Yes.

Q. That means they can't keep her within a safe range, right?

A. Correct.

Q. And if we look at the next page, 9009-581: Patient is

sporadic and supratherapeutic on coumadin since 2008 until present.

That's what Dr. MacFarland says in October of 2011, right?

A. Yes.

Q. That's what she said to justify the switch from warfarin to Pradaxa in 2011, right?

A. Yes.

Q. Warfarin wasn't working for her. Warfarin wasn't working for Mrs. Knight. Do you agree with that?

A. That's what the record reflects. It depends on what you mean by not working. It was given to prevent stroke. I don't see a record here that she had any stroke during the coumadin period.

Q. You would agree with me that Dr. MacFarland is expressing an opinion here that she needs to go off warfarin because she can't control the therapeutic range with Mrs. Knight, correct?

A. That's correct. That statement is correct.

Q. It doesn't say anything about a TV ad in this document --

A. Uh-huh.

Q. -- right?

A. Correct.

MR. LEWIS: All right. Now let's talk about -- you reviewed the records -- I'm finished with that. Thank you very much.

Q. You reviewed the records for Mrs. Knight's Pradaxa use,

correct?

A. Yes.

Q. And you're familiar with the fact that before this stent procedure in April of 2013, so between October of 2011 and April of 2013, Mrs. Knight was on Pradaxa, correct?

A. Correct.

Q. Okay. And in April of 2013, she had a stent procedure, correct?

A. Correct.

Q. We're going to talk about that in a second.

But between October of 2011 and April of 2013, while Mrs. Knight was on Pradaxa, she didn't suffer a stroke, and she didn't suffer a bleed event, correct?

A. Correct.

Q. And that's 18 months, correct?

A. Correct.

Q. And then something happened in April of 2013, correct?

A. Correct.

Q. She had a stent procedure.

And if we go to 9007-94 --

A. 9007 --

Q. 9007A-94. This is April 22nd, 2013, from Dr. Maru, right? Referring physician, Dr. Graham.

A. Yes.

Q. Okay. Now, just to help orient the jury, by this time Dr.

MacFarland is no longer treating Mrs. Knight, correct?

A. It seems like it.

Q. She has switched physicians by this time, correct?

A. Okay.

Q. And so the decisions on prescribing Pradaxa in 2013 are no longer being made by Dr. MacFarland, correct?

A. Yes.

Q. Other physicians are involved in this, correct?

A. Yes.

Q. All right. And you see here in the procedure, bare metal stent -- again, that's a stent placed to avoid having to be on blood thinners too long, correct?

A. Yes.

Q. Okay. Was placed.

And if we go to 9007-0095, we see under Conclusion a recommendation: Continue aspirin indefinitely and Plavix for a minimum of four weeks, preferably longer if the patient can tolerate it. Resume her Pradaxa tonight.

Now let's look at what the next line says.

By the way, Dr. Maru is a cardiologist. Did you know that?

A. From the record.

Q. Okay. Due to triple therapy -- and you know what triple therapy is, right?

A. Yes.

Q. That's aspirin, Plavix and Pradaxa. That's called triple therapy, right?

A. Yes. In her case, yes.

Q. In her case. It might mean something different in a different context.

A. Yes.

Q. Okay. Due to triple therapy, I am not sure the patient will tolerate long-term Plavix, so minimum would be four weeks, and that's the main reason bare metal stenting was chosen during this PCI procedure.

Do you see that?

A. Yes.

Q. Okay. So the doctor here is concerned that it's the Plavix that Mrs. Knight won't tolerate in this triple therapy, right?

A. That's what he says.

Q. And that's the thing that is going to change here in April of 2013, right?

A. That's what he said. He added Plavix, yes.

Q. Because during the 18 months that Mrs. Knight was on Pradaxa before the stent procedure, she was taking Coreg, right?

A. According to the record.

Q. She was taking aspirin, right? Omeprazole, a P-gp inhibitor?

A. Yes.
Q. Coreg is a P-gp inhibitor?
A. Yes.
Q. She was taking those medications from October of 2011 to April of 2013, right?
A. That's true.
Q. No stroke, no bleeding, correct?
A. Yes.
Q. The one thing that changed was adding Plavix to the medication profile in April of 2013, correct?
A. Yes.
Q. That's what changed.
And you would agree with me that Plavix has a risk, independently of being mixed with Pradaxa or aspirin, of bleed?
A. Yes.
Q. Just like other anticoagulant medications, Plavix too has a risk of bleeding?
A. Yes. All of them do.
Q. All of them do.
And when you mix more than one blood thinner, you increase the risk of bleed?
A. That's true.
Q. Okay. And when you increase the risk of bleed with other risk factors such as age, you're compounding the risk of

bleed, correct?
A. Correct.
Q. But you don't criticize the decision to put Mrs. Knight on Plavix, Pradaxa and aspirin in April of 2013, do you?
A. I'm not in that position to make a decision. The cardiologist put a stent, and he wanted to protect the stent, so that's his decision.
Q. Right.
Because once you put in a stent, you run a higher risk of stroke, right?
A. Not from the stent, no. He put the Plavix to prevent the stent from clotting.
Q. Correct.
You have a high --
A. But the stent doesn't cause a stroke.
Q. You have a higher risk of blood clots, correct?
A. In the stent.
Q. Correct, with a stent.
A. In the stent.
Q. Yes, in the stent --
A. Yes.
Q. -- itself. Okay. Let me get this right. Thank you for correcting me.
When you put in a stent, you run an independent risk of higher risk of blood clots in the stent, correct?

A. Yes.
Q. Okay. And to counteract that, physicians will sometimes prescribe Plavix; is that right?
A. Yes.
Q. Okay. So at the time that Mrs. Knight is having her stent procedure in April of 2013, the doctor is concerned about blood clots because of the stent, right?
A. Yes.
Q. She still needs an anticoagulant like Pradaxa, right?
A. Yes.
Q. And they're giving her aspirin as well because they are concerned about the stroke risk, right?
A. Correct.
Q. Okay. But, of course, that comes with a higher risk of bleeding, right?
A. Correct.
Q. And these doctors are trying to make difficult decisions with a patient who has lots of risk factors, right?
A. Correct.
Q. Fair to say?
A. Uh-huh. Correct.
Q. Okay. And it is another one of those darned if you do, darned if you don't situations, correct?
A. It is difficult.
Q. All right. And, of course, you have already covered some

of the documents related to -- and I'm finished with that -- Mrs. Knight's bleed event that took place in May of 2011, right? You covered that.

Okay. You know that she was treated by a GI specialist called Dr. Huh; is that right?

A. Yes.

Q. Okay. So let me see if I can get some of these facts out.

Mrs. Knight was brought in to see Dr. Abdelgaber after she had witnessed some bleeding for about six days.

Do you recall that?

A. Yes. Yes.

Q. Okay. So she had been experiencing some bleed symptoms for about six days, correct?

A. I'm not sure if it's six. It says a few days --

Q. A few days.

A. -- in the record, yes.

Q. Okay. So a few days before she sees Dr. Abdelgaber, correct?

A. Yes.

Q. And then when she sees Dr. Abdelgaber, he refers Mrs. Knight to Dr. Huh, correct, the GI specialist?

A. Yes.

Q. Okay. And Dr. Huh on May 20th of 2013 sees Mrs. Knight, correct?

A. Yes.

Q. He assesses her?
A. Yes.
Q. She was in stable condition, correct?
A. I have to look at the record.
Q. Go ahead.
A. Was that that time she was admitted?
Q. Correct.
A. Yeah. The gastroenterologist saw her after she received the blood.
Q. Absolutely.
A. So she was relatively stabilized.
Q. Okay. She was stabilized.
And in fact, Dr. Huh did not immediately perform a procedure on Mrs. Knight --
A. That's correct.
Q. -- is that correct?
He actually let her stay in the hospital overnight, correct?
A. Yes.
Q. And said that I'm going to handle this procedure in the morning, correct?
A. Yes.
Q. And then the next morning, Dr. Huh came in, and he did a colonoscopy, correct?
A. Yes.

Q. And he found when he did the colonoscopy an AVM, correct?
A. Yes.
Q. And he treated it, correct?
A. Yes.
Q. He stopped the bleeding?
A. Correct.
Q. He stabilized her?
A. Further, yes.
Q. Within 24 hours of presenting to Dr. Huh, Mrs. Knight was stabilized, and her AVM was treated, correct?
A. Correct.
Q. And it was treated successfully at that time, correct?
A. Correct.
Q. The bleeding stopped?
A. Correct.
Q. Okay. She was allowed to leave the emergency situation of having an AVM that needs treatment, correct?
A. Correct. For the AVM, yes.
Q. For the AVM.

It was -- it was repaired, right?

A. Yes.
Q. Okay. That would be a successful repair of an AVM by your own definition, correct?
A. Yes. If you clip it, and the bleeding stops, then the job is done.

Q. Okay. Now later on that year, 2013, there's a question about whether or not Mrs. Knight should go back on the Plavix, isn't there?

A. Yes.

Q. And then if we go to 9007-146, this is from August 23rd of 2013, and we see this is one of the doctors -- referring is Dr. Abdelgaber, and one of the consultants is Dr. Snavely. You see the reason for consultation is elevated troponin.

That is suggestive of a possible heart attack, isn't it, Doctor?

A. Yes.

Q. When there is elevated troponin, it's a big red flag for physicians that a patient may be experiencing a serious heart condition, correct?

A. Yeah. Depending on the clinical scenario, but yes.

Q. Okay. And we see that in the third paragraph, it says: The patient states that she's been doing fairly well in her typical state of health, but she did begin to have some heart -- some chest pains essentially, correct?

A. Yes.

Q. Okay. And when we go to 9007-148, 9007A-148, we see there's a plan.

A. Yes.

Q. And you see that the doctor talked to her son, Mr. Knight, all on the phone, and that she had had a similar presentation

in July. You see where it says that?

And Dr. Gunnalaugsson is the cardiologist who said that they should take a conservative approach. You see that?

A. Yes. Yes, I see that in the last paragraph under Plan.

Q. Right.

A. Yes.

Q. Well, let's look at what he says at the bottom: It should be noted that Dr. Gunnalaugsson did not want her back on Plavix due to the history of gastrointestinal bleeding.

You see where it says that?

A. Yes.

Q. This cardiologist is afraid to put her on Plavix, right?

A. Yes.

Q. Because he's worried that what happened in May is going to happen again, correct?

A. Yes.

Q. And he says: Will keep her on low-dose aspirin along with Pradaxa.

He's not afraid of Pradaxa at this point in time, correct?

A. That's what his note says.

Q. Okay. He's afraid of Plavix, correct?

A. Yes.

Q. And he says: As I do not think Pradaxa could be held in the long term given her multiple issues with blood clot, correct?

A. The issue here is to compare between the need for Pradaxa versus Plavix. She passed the month since the stent was put in, right? Help me out here.

Q. Well, let me try to help you out with a couple of questions, see if we can get those answered first.

So this note reflects that Dr. Gunnalaugsson said, ah, did not want her back on Plavix due to the history of gastrointestinal bleeding, correct?

A. Yes.

Q. Plavix could potentially treat a problem that she was having with the stents at this time if she was having a problem, correct?

A. Correct.

Q. Okay. If she was having -- if the cardiologist felt she was having a problem with the stent, Plavix could help treat that, right?

A. Correct.

Q. And Dr. Gunnalaugsson is saying don't do that, I'm afraid of a bleed, correct?

A. Correct.

Q. But he is saying go ahead and keep her on Pradaxa because I'm worried about stroke and blood clots, right?

A. Yes.

Q. He's not afraid of a bleed with Pradaxa at this point in time, correct?

A. To me that not really is concerning. Because if they believe this troponin is an indicator of a heart attack, then she didn't really need the Plavix. Maybe he's just not convinced of it. Because I wouldn't want somebody bleeding if they have a heart attack, because they will die first from a heart attack. So to me, this -- this record really contradicts itself.

Q. My question is this.

The physician that was treating her and had seen her many, many times before this point in time -- right?

Dr. Gunnalaugsson --

A. Yes.

Q. -- a cardiologist --

A. Yes.

Q. -- in the field of working heart conditions, correct?

A. Yes.

Q. He concluded to stay on Pradaxa and not take Plavix, correct?

A. Yes.

Q. And the reason he made that decision was that he was afraid that Plavix could trigger a bleed, correct?

A. Yes.

Q. And he was not afraid of that, according to this note, with Pradaxa, correct?

A. Yes.

Q. And in fact, if we go to 9005A-5 --

A. 9005A-5.

Q. Do you see on 9005-5, we've got a note from August 29 of 2013?

A. Yes.

Q. And this is from Dr. Gunnalaugsson, and the primary care physician is Dr. Abdelgaber. And you see: She was hospitalized with anemia due to GI bleed. She was eventually surprisingly put back on Pradaxa.

You see where it says that?

A. Yes.

Q. Okay. She has been off Plavix. I have suggested her not to take aspirin given the situation, correct?

A. Yes.

Q. That's what it says.

Worried about a bleed, correct?

A. Yes.

Q. Later on, it says: We had done a nuclear stress test last year, and then she had a coronary intervention earlier this year.

That would be the stent, correct?

A. Yes.

Q. Okay. And was put on Plavix which probably triggered her bleed.

Right in the record, right? You see that?

A. That's what he is saying, yes.

Q. That's what he is saying.

Plavix triggered the bleed according to this physician who treated Mrs. Knight during this time frame, correct?

A. That's what he says.

Q. And you disagree with that?

A. No, I'm not saying that. The issue with Pradaxa is how much you bleed, not what triggers the bleeding. I mean, you can bleed for 5 or 6 cc's or half a unit. The issue is life-threatening blood, a hemoglobin of 6.

So the trigger could be anything. Anything can -- you know, it could be the straw that breaks the camel's back.

Q. So you agree --

A. But it's not because the straw is so heavy. It just happens to be the back is just about to break.

You know, the camel's back is about to break --

Q. Doctor --

A. -- and you just added a straw.

Q. Doctor, yes or no, do you agree with this doctor's conclusion that Plavix probably triggered her bleed? Yes or no?

A. I can't tell. It could be. I cannot say right or wrong. It could be.

Q. All right. And if we look at 9005-6, which is the next page.

A. Yes.
Q. And on August 29th, 2013, this doctor concludes -- this is 9005A-6.
A. Yes.
Q. She will remain on Pradaxa since she is tolerating this right now.
You know what tolerating means?
A. Yes.
Q. It's working for her, right?
A. That she's able to take it without much problems.
Q. Right.
She's not experiencing side effects or complications, right? Correct?
A. Yes. That's what he says, yes.
Q. And it's working. It's effective for her, right?
A. Yes.
Q. That's what this doctor is concluding on August 29th of 2013, correct?
A. Correct.
Q. Yes or no, do you agree with this doctor's conclusion about Pradaxa being tolerated by Mrs. Knight at this time?
A. Tolerated as meaning preventing stroke or not causing side effects?
A. Both.
Yes or no, do you agree with this doctor's conclusion or

not?

A. So far at this point, correct.

Q. Okay. Now --

MR. LEWIS: I am finished with that exhibit. Just a couple more topics, Doctor.

Q. You have testified that Mrs. Knight was over-anticoagulated? Is that the right term?

A. Yes.

Q. Okay. And none of the records that we just reviewed used the word over-anticoagulated on Pradaxa, do they?

A. I did not see it.

Q. It's not in there, is it?

A. I didn't see it.

Q. And you would have pointed that out if it was in there, wouldn't you have?

A. I would have.

Q. I figured, yeah.

But you base that conclusion on an aPTT test that was run on May 21st of 2013, correct?

A. Yes.

Q. After Mrs. Knight had a bleed event that was fixed or repaired, treated, right?

A. Yes.

Q. Okay. And you're saying that, based on that aPTT test, she was over-anticoagulated some day before that?

A. Yes.
Q. Okay. But you don't have an aPTT test to prove that, do you?
A. The day before, no, I don't.
Q. Okay. Or the week before?
A. It's true. Whatever is in the record is what I have.
Q. Okay. Just the one after --
A. Yes.
Q. -- of 47?
A. Yes.
Q. Okay. But you know several times throughout Mrs. Knight's history with anticoagulant medication, she's been over 47.
You know that, right?
A. Yes.
Q. And in fact, if we go to the aPTT test from opening statement -- and these are in the record, but this is a demonstrative.
This is a demonstrative that shows in the record all of the instances where Mrs. Knight, while on warfarin, had similar or higher aPTT tests, right?
A. Yes.
Q. On at least six different occasions while on warfarin, Mrs. Knight had higher or the same -- 46.1. The other five are higher, right?
A. Yes.

Q. The fact is that your conclusion that Mrs. Knight was over-anticoagulated at the time of a bleed that had apparently started several days before, the fact is you're guessing, right?

A. Yes.

MR. LEWIS: All right. I'm finished with that exhibit.

Q. The last subject, Doctor, is Mrs. Knight passed away on September 2nd of 2013, correct?

A. Yes.

Q. Okay. I want to ask you about a document, a medical document that was associated with that time frame. Okay?

A. Yes, sir.

MR. LEWIS: I'm going to move for the admission of 9001.

(Counsel conferring.)

MR. CHILDERS: No objection, Your Honor.

THE COURT: It's admitted.

(DEFENDANT'S EXHIBIT 9001 ADMITTED INTO EVIDENCE.)

BY MR. LEWIS:

Q. Doctor, you would agree with me that filling out a certificate, a death certificate -- have you ever filled out a death certificate before?

A. I did on more than one --

Q. You know that is something that is required by law?

A. Yes.
Q. It is supposed to be accurate, truthful?
A. Yes.
Q. Okay. And you know Dr. Abdelgaber filled this out for Mrs. Knight?
A. Yes.
Q. Okay. And if we look in the center, the doctor has to indicate what the immediate cause was --
A. Yes.
Q. -- right?
And, again, this isn't something that was covered during Dr. Abdelgaber's deposition. You probably haven't -- have you seen this document before?
A. I'm not sure.
Q. Okay. You see that Dr. Abdelgaber -- that was her treating physician at the time, right
A. Yes.
Q. Okay. And he indicates cardiopulmonary arrest.
Do you know what that is?
A. Yes.
Q. That's a heart attack, right?
A. The second one is the heart attack.
Q. Okay. Cardiopulmonary arrest?
A. Is when both the heart and the lungs stop.
Q. And due to or as a consequence of acute myocardio

infarction, that's a heart attack?
A. Yes.
Q. And then it also indicates coronary artery disease, something that Mrs. Knight unfortunately had been struggling with for a number of years, correct?
A. Yes.
Q. And what's that last --
A. Hyperlipidemia.
Q. What is that?
A. I think this is just a comorbid condition he listed. It is when your triglycerides or lipids and cholesterol is elevated.
Q. And you see that other significant conditions attributing to death are listed even below that, right?
A. Yes.
Q. And it doesn't appear to have any kind of a limit on how many can be listed there, right?
A. No. You can list as many as you want.
Q. And he lists four of them, right?
A. Yes.
Q. CHF, do you know what that stands for?
A. Yeah, congestive heart failure.
Q. HTN, hypertension?
A. Yes.
Q. CKD, chronic kidney disease?

A. Kidney disease, correct.
Q. And dementia?
A. Yes, sir.
Q. Dr. Abdelgaber doesn't mention a GI bleed or Pradaxa in any way, does he?
A. Not in this certificate, he does not.
MR. LEWIS: I'm finished with that. I just have, like, five or ten minutes left.
Doctor, I just want to ask you about warnings, which is something that you covered in your direct examination.
Q. You've reviewed the Pradaxa label, correct?
A. Correct, sir.
Q. Okay. And you know that the decisions to put Mrs. Knight on triple therapy after the stent procedure were made in April of 2013, right?
A. Yes.
Q. By physicians other than Dr. MacFarland --
A. Yes.
Q. -- right?
And those physicians had to make that difficult decision as to whether and how much blood thinner to put Mrs. Knight on after her stent procedure, right?
A. Yes.
Q. That was a very difficult choice?
A. Yes.

Q. Okay. Sometimes there's no easy answer to some of these difficult choices on risks and benefits?

A. Correct.

MR. LEWIS: I don't think 5889 has been admitted, but that is our label from April of 2013.

MR. CHILDERS: No objection.

THE COURT: It's admitted.

(DEFENDANT'S EXHIBIT 5889 ADMITTED INTO EVIDENCE.)

BY MR. LEWIS:

Q. So you've reviewed the label for physicians, like the physicians who would be prescribing triple therapy in April of 2013, for Pradaxa, haven't you?

A. Yes.

Q. Okay. And there's no question about it in the Warnings and Precautions, the physicians are well aware and made aware that there is a serious risk of bleeding, correct?

A. Correct.

Q. Okay. And there's no question that for those physicians making that difficult decision in April of 2013, under Drug Interactions right on the front page: P-gp inhibitors in patients with severe renal impairment, Pradaxa use is not recommended.

It's right there on the first page, right, Doctor?

A. Was that present at the time she was prescribed the medicine?

Q. I'm talking about in April of 2013.

April of 2013, this is --

THE COURT: He's referring to tab 5889.

MR. LEWIS: You see it was revised --

THE COURT: It's in the notebook.

THE WITNESS: I see. And at that time it was, yes.

BY MR. LEWIS:

Q. In April of 2013, those physicians who had to make the decision to put Mrs. Knight on triple therapy after the stent procedure, they're going to have this label in April of 2013, right?

A. Yes.

Q. And you would agree that they should have read it, right?

A. Yes.

Q. And a good doctor will read the label periodically, right?

A. This label has changed. I think that's the problem here. Because if you read it one time, you may not know that it was changed if nobody told you.

Q. Doctor, you see that this was a label that was in existence at the time that Mrs. Knight was prescribed Pradaxa in April of 2013, correct?

A. Correct.

Q. All right. And you see that -- you would agree with me that a good doctor will review labels for medications on occasion, right?

A. Correct.
Q. Okay. And right there on the front page, it says recent major changes. Right on the first page, right?
A. Correct.
Q. Okay. And this label right on the first page: P-gp inhibitors in patients with severe renal impairment, Pradaxa cannot be recommended, correct?
A. Correct.
Q. Okay. And you would agree with me that a physician who is prescribing Pradaxa in April of 2013, who read this label, would know about that risk, correct?
A. I would assume so.
Q. Okay. And you also agree with me that sometimes doctors have to make difficult choices to prescribe medication in the face of risk, right?
A. Correct.
Q. To avoid other risks, right?
A. Correct.
Q. And you don't have any criticism, do you, of the doctors who had to prescribe Mrs. Knight triple therapy in 2013?
A. Actually I do.
Q. Okay. You don't think they should have put her on triple therapy?
A. The record actually has a little bit of contradiction. On one side, they said she had a heart attack, but then they go

ahead and say we don't want to give her the Plavix, but then the death certificate says she died of a heart attack. If you add all these together, it doesn't add up.

So I think there is -- I have a couple of issues with that. If you believe she has a heart attack, and that's the imminent risk for her, then you should keep Plavix and maybe stop Pradaxa. But that's not what they did, and they said because of fear of GI bleeding. But then they say she had elevated troponin. So I'm a little concerned about that.

Q. You would agree with me that the decision that the physicians had to make in April of 2013 was a difficult one?

A. I agree with that.

Q. Mrs. Knight had serious risks of blood clots, stroke and heart disease, correct?

A. Correct.

Q. And she also had a history of bleeding and anemia, correct?

A. Correct.

Q. Okay. And so the decision on what medications to put her on and how much was a difficult one, correct?

A. It was.

Q. Okay. But there's no question in your mind that those physicians should have been aware that there's a risk of bleeding when those medications were prescribed, correct?

A. Correct.

Q. Okay. And in fact, if we go to 5889-12, there's a Medication Guide for Pradaxa, and this is for the patients.

And this is also received by those physicians, correct, 5889?

A. Yes, the Medication Guide for Pradaxa.

Q. Right.

And Medication Guides are received by physicians, correct?

A. Correct.

Q. Okay. And if you look down, scroll down to you may have a higher risk --

A. Yes.

Q. -- over 75 years old, that was something that Mrs. Knight had a higher risk of bleeding --

A. Yes.

Q. -- correct?

Kidney problems, a higher risk of bleeding, correct?

A. Yes.

Q. And specifically mentions on the fifth bullet point down Plavix --

A. Yes.

Q. -- correct?

A. Correct.

Q. And so the very risk that is contained in this warning document to physicians and patients occurred with Mrs. Knight, correct?

A. Correct.

MR. LEWIS: That's all I have at this time, Your Honor.

(Defense counsel conferring.)

MR. LEWIS: Your Honor, actually my co-counsel indicated that I haven't moved in 9005A, and so I move for the admission. It's a medical record subset, and I apologize for that.

THE COURT: Any objection?

MR. CHILDERS: Not if it's a medical record, Your Honor.

THE COURT: It's admitted.

MR. LEWIS: Thank you.

(DEFENDANT'S EXHIBIT 9005A ADMITTED INTO EVIDENCE.)

THE COURT: All right.

REDIRECT EXAMINATION

BY MR. CHILDERS:

Q. Doctor, I'm going to move up here because I'm going to use the Elmo to ask you some questions, follow-up questions.

Okay?

A. Okay.

MR. CHILDERS: I'm sorry. Neal knows how to use it, and I don't. Let me start with this before we get to the Elmo. I'm sorry.

Gina, could you pull up --

Q. So this is the label that you were just asked about, that April of 2013 label, correct?

A. Correct.

Q. And it says that patients on P-gp inhibitors with severe renal impairment, Pradaxa use not recommended.

Do you see that?

A. Correct.

Q. And then it tells the physician Section 7 is where they can go look to get more information, right?

A. Yes.

MR. CHILDERS: Could you take us to Section 7, Gina. Blow that up.

Q. Tell the jury where it says Coreg or carvedilol in this section.

A. I don't think it is present.

Q. Again, you told us earlier Coreg is a common medication for atrial fibrillation patients?

A. Yes, it is.

Q. And you told us about it being a P-gp inhibitor.

So my question to you is, did you know it was a P-gp inhibitor before you looked into it for this case?

A. Not really.

Q. How many P-gp inhibitors are there?

A. Oh, a lot, a long list of them.

Q. Dozens and maybe more?

A. I can only remember the ones that I prescribed in my medical practice, including the proton pump inhibitors, like your Prilosec and Prevacid, because I prescribe those. I know about a couple of antibiotics because I run into those commonly. But there's a lot of others I didn't even know about until I read this case.

Q. Coreg being one of them?

A. Yes.

Q. Okay. And if there's a medication that you know is often given to a patient population who's going to take a medicine like Pradaxa, do you expect as a physician that the drug company is going to tell you if there's an interaction with that drug?

A. Yes.

Q. Okay. And in this label, does the word Coreg appear anywhere?

A. I don't see it.

Q. Does the word -- and carvedilol is the chemical name for it, the generic name?

A. Yeah. I don't see it here.

Q. That's not in there either, right?

A. No.

Q. Okay. Doctor, have you misrepresented anything to this jury?

A. No, not to my knowledge.

Q. And do you agree with me it wouldn't be fair for counsel to misrepresent anything to this jury either, would it?
A. That's a question better addressed to him.
Q. I'm sorry?
A. That is a question to him. It's not good to misrepresent anything in this courtroom, I believe.
Q. You swore to tell the truth. You swore an oath, right?
A. Yes.
Q. And do you understand the lawyers here, we do that every day when we walk into court, we have to tell the truth?
You understand that?
A. Yes.
Q. Okay. This chart that Mr. Lewis showed you, he said look at all of these aPTT readings from when Mrs. Knight, Betty Knight was on warfarin.
Do you remember that?
A. Correct.
Q. Let me show what those readings actually are. Okay?
I'm going to save the first one for last. The first one says April 9th, 2009. I'm going to save that for last. I'm going to start with September 16th, 2010.
He said the aPTT test was 51. Do you see that on here?
A. Yes.
Q. And the jury was told that in opening statement, too.
Remember he told you that?

A. Yes.

Q. All right. Let's look at that record.

Doctor, is aPTT even measured on this test -- on this sheet?

A. No. That's a pro time INR measurement.

Q. That is not an aPTT test, is it?

A. No, these are two different things.

Q. The PT is part of the INR test, correct?

A. The INR is a reflection of the pro time, and this is what we use to monitor for patients who are on coumadin. The aPTT is not used to monitor people on coumadin.

Q. Okay. Let me show you -- I'll show you again this chart.

So the next one that he told you had an aPTT of 16.6 was June 8th, 2011. Do you see that?

A. Yes.

Q. Let's look at that record.

June 8th, 2011, do they measure the aPTT?

A. I don't see it. I see a pro time, PT.

Q. And the PT is 16.6, the number that Mr. Lewis told this jury was her aPTT reading, correct?

A. No, these are two different things.

Q. Right.

All right. Let's look at the next one. 8/17/11, do you see that the chart says her aPTT was 46.1 that day?

A. Yes, I see it.

Q. All right. Let's look at that record.

46.1, is that the aPTT or the PT?

A. I do not see an aPTT here.

Q. Okay. That's not the same test, is it?

A. No, it's not.

Q. Okay. The next one, he says on 10/13 -- I may have missed one. On 10/13/2011 -- and I'll try to find this one that says 96.2.

It says the aPTT was 75.7. Do you see that?

A. Yes.

Q. Let's look at the test. It's not the test actually. It's a message from Dr. MacFarland's office.

What does she say was 75.7?

A. The pro time.

Q. Is that the same as the aPTT?

A. They are different measurements.

Q. Okay. Now I said I was going to save the first one for last, and there's a reason for that.

Do you see that on April 9th, 2009, it says the aPTT was 62 on this chart?

A. Yes.

Q. And you recall I think in your -- in the deposition of Dr. Abdelgaber, do you remember he said she had an aPTT of 62 when she was on Pradaxa when it was measured once, correct?

A. Yes.

Q. All right. Let's look at that record.

Now on this one, they actually did measure her aPTT. Do you see that?

A. Yes.

Q. And it was 62, right?

A. Yes.

Q. What was her INR that day?

A. 4.3.

Q. Was she over-anticoagulated that day, Doctor?

A. Yes.

Q. That's a clear sign to you that she was over-anticoagulated because of the INR, right?

A. By all measures.

Q. There's no question about that?

A. That's true.

Q. And her aPTT was 62 that day, correct?

A. Yes.

Q. I'm going to show you the demonstrative -- not demonstrative, I'm sorry -- this chart that Mr. Lewis showed you.

Do you recall that?

A. Yes.

Q. And he asked you didn't her INRs fluctuate during this time period, correct?

A. Yes.

Q. Did Betty have a bleed at any point during this time period?

A. Not that was documented, no.

Q. And I'm going to get to that in a minute.

Did she have a stroke at any point during this time period?

A. No.

Q. Does INR fluctuation somehow make Pradaxa an appropriate medication for a patient with severe renal impairment who is also taking a P-gp inhibitor?

A. That is not enough reason to switch.

Q. When Dr. MacFarland actually switched Betty to Pradaxa, did the label tell her don't give this medicine to a patient who has severe renal impairment and is taking a P-gp inhibitor?

A. No. It was not in the label at that time. It was added on later.

Q. Did the label ever tell physicians Coreg is a P-gp inhibitor?

A. It does not.

Q. I want to show you about the chronic bleed again. This is is the record you were shown from Dr. Gunnalaugsson from December 5th, 2008.

Can you see that?

A. Yes.

Q. That's after the hospitalization where the warfarin was stopped, correct?

Wasn't that in November? I'm sorry, Doctor.

A. I believe so, yes.

Q. Okay. And he says that it was stopped because of a chronic bleed.

You looked at all of the records themselves, and we went through them with the jury, correct?

A. Yes.

Q. Was there any evidence on the record of anyone actually seeing a bleed?

A. No. It was assumed --

Q. And we --

A. -- but not documented. Nobody found bleeding at that time.

Q. Okay. Let's show you what was shown right early on in your testimony on cross.

This was the coumadin label. Do you remember that?

A. Yes.

Q. And Mr. Lewis asked you, isn't it true that the bleed warning is in this box up front? Do you remember that?

A. Correct.

Q. And I think he asked you, isn't that a good warning.

Do you recall that?

A. Yes.

Q. Wouldn't that be a good warning for Pradaxa to have to tell doctors that there's a serious, serious risk here and draw it right to their attention right at the top?

A. I believe so.

Q. Does it --

A. It should be.

Q. Does it have a warning like that?

A. Not in there. Not in their information, it does not.

Q. Okay. I want to ask you about when Betty was switched from warfarin to Pradaxa. Okay? I'm going to show you these records that were in the binder that you have up there.

The first one was where Rick actually called the office, and I think we saw this during Dr. MacFarland's deposition, saying, hey, I'd like to talk to you about a new drug to replace coumadin.

Do you recall that?

A. Yes.

Q. Okay. And that was on the 17th of October 2011.

Do you see that?

A. Yes.

Q. And then it says: We want to talk before we come in today. They're coming in at 3:00 today for an appointment.

Do you see that?

A. Yes.

Q. And then we have the record you were shown from that

actual appointment, right?
A. Yes.
Q. The same day, 10/17/11?
A. Yes.
Q. Where it says want to replace coumadin with new med Pradaxa, is that under the Chief Complaint section of the record?
Do you see that just above --
A. Yes.
Q. And then --
A. Want to replace coumadin.
Q. It says sleeps all the time. Do you see that?
A. Yes.
Q. The chief complaint section, is that information the patient gives to the doctor or is that information the doctor is giving to the patient when you write the chief complaint?
A. It's what the patient tells us.
Q. Okay. And what does this tell you -- tell us that the patient said she wanted to replace coumadin with?
A. That's what it said.
Q. With what?
A. With Pradaxa.
Q. Specifically asked for Pradaxa?
A. Yes.
Q. Let me show you this express scrips that we were shown,

too, where it was the authorization form for Betty to get Pradaxa.

Do you recall that?

A. Yes.

Q. And as a doctor, you know that sometimes when you prescribe a medication, it's not going to be covered, and so you have to fill out a form to tell the company why you want it for that particular patient?

A. Yes.

Q. At the time that -- this is dated October 18th, 2011.

At the time that this was written and sent by Dr. MacFarland, did the Pradaxa label tell her Pradaxa was not an appropriate medication for a patient with severe renal impairment who was taking Coreg?

A. Not at that time, no.

Q. Okay. If a doctor -- you as a doctor, if you were to fill out one of these forms that said my patient wants to switch medicine because they say a TV ad, do you expect that the insurance company is going to cover it for that reason?

A. No.

Q. All right. Let me show you the Gunnalaugsson record that you were asked about there at the end.

Notes that she had been hospitalized with severe anemia due to GI bleed, right?

A. Yes.

Q. And then it says she was eventually surprisingly put back on Pradaxa. Do you see that?

A. Yes.

Q. Is that a surprise -- does that surprise you, too?

A. Yes. If they assumed there was a GI bleed or they proved there was a GI bleed, then they shouldn't have put it.

Q. And does this tell you what he thought about that?

What does it tell you about what he thought about her being back on Pradaxa when he says surprisingly?

A. He said something about the Plavix, which probably triggered her bleeding.

Q. And that's what I wanted to ask you next.

Triggering the bleed, you don't dispute that Plavix could have triggered the bleed, right?

A. Could be Plavix or aspirin, either one.

Q. Explain to the jury why you think Pradaxa was the most substantial factor in the bleed and the extent of the bleed and the damage it did to Betty.

A. Anybody can bleed from trivial things. You can cut yourself when you are shaving or anything. It's the issue of what stops you or does not stop you from bleeding.

I think her blood was too thin than what she had any reason to bleed whatsoever. In this case, the AVM maybe touched by the aspirin, then the bleeding would not stop. You open the faucet, and you cannot stop it because the plug is

the fibrin. To make a clot, you need thrombin and fibrin. Well, guess what, the Pradaxa prevents you from making that clot because it inhibits the thrombin.

So you have got a faucet that is oozing. Now it's bleeding, it is wide open, and you need a plug. Well, the plug is made of fibrin and thrombin, and Pradaxa prevents those from working. So the blood is too thin to make the plug to stop the bleeding.

You can trigger the bleeding by anything, but the body has mechanisms to stop bleeding. In this case, she had Pradaxa which prevents the body from making the clot or the plug to stop that faucet that is bleeding. So that's the difference.

MR. CHILDERS: Could we go back to the label, Exhibit No. 88, which was the 2012 label. Page 4, if you could.

THE WITNESS: Is that in your folder or --

MR. CHILDERS: That's my fault, not yours.

Oh, I'm sorry. It's in my folder, yes.

THE WITNESS: Your folder. Okay. And direct me to that page again. I'm sorry.

MR. CHILDERS: Exhibit 88, page 4. This is the Pradaxa label.

If you could blow up the very first sentence at the top, Gina. I'm sorry. The first two sentences. Highlight that second sentence for me.

Q. You had told the jury you thought that Betty Knight likely

would not have had a bleed or at least a bleed to the extent she did if she had been on warfarin.

Do you remember that?

A. Yes, I do.

Q. Okay. I want to show you in the label -- do you see here where it says: There is a higher rate of major gastrointestinal bleeds in patients receiving Pradaxa 150 milligrams than in patients receiving warfarin. And then it says 1.6 versus 1.1.

Do you see that?

A. Yes.

Q. Okay. How does that play into your opinion about whether or not she would have had a bleed like this on warfarin?

A. I believe it would not have been life-threatening like it was.

Q. And how does this particular information, ah, feed into your --

A. That supports my opinion that there is higher incidence of GI bleeding, gastrointestinal bleeding with Pradaxa compared with warfarin.

In this particular case, we know that she was on warfarin for years. We know that even if she bled, it would minimum ooze, never had a life-threatening condition where her hemoglobin dropped down to 6.

So I have the data that supports my opinion that it is

more likely to bleed with Pradaxa than coumadin. From her own history as a patient, she was on coumadin for years. She did not have any life-threatening bleeding. She never had documented bleeding. With Pradaxa, her bleeding almost led to her demise when her hemoglobin dropped to 6.

So that supports my opinion.

Q. Can you remind the jury what organs filter Pradaxa out of your body?

A. It is cleared by the kidneys. So when you have kidney failure or your kidneys are not working well, then you don't clear the medication out of your system as fast.

Q. And warfarin, is that cleared through the kidneys or a different organ?

A. Usually it is metabolized in the liver.

Q. Okay. So if you have a patient who has kidney problems, does that affect their warfarin level like it does with Pradaxa?

A. No. Usually it will affect Pradaxa more.

Q. The jury heard, and you read, Dr. MacFarland's deposition. They heard it this morning when she said that Betty would get dehydrated sometimes, and that would cause her kidney function to go down.

Do you recall reading that?

A. Yes.

Q. How is that significant as it relates to her using Pradaxa

as an anticoagulant versus warfarin?

A. Well, it will affect it, and it will cause a fluctuation in the level simply because we rely, as physicians, on certain measurements to tell you how well your kidney is working. And that blood measurement reflects the function of your kidney at that point in time when the blood test was done. So if you are a sick person like Mrs. Knight, and you have multiple medical problems and episodes of dehydration, then your kidneys could have been a lot worse than they are when you came to the doctor.

Because usually when you come to the doctor for a routine visit, you probably will get dressed and have breakfast and drink. Maybe on a different day, your actual creatinine clearance will be even much worse, and you will not know it. So that fluctuation will lead to a fluctuation in the medication level and the degree of anticoagulation or over-anticoagulation.

It could happen anytime between doctor visit and you not knowing about it --

Q. Anytime --

A. -- because you really don't have a way of measuring it.

Q. Anytime her kidney function decreased because she was dehydrated, what would you expect to happen to her Pradaxa level?

A. Probably went up.

Q. Okay. And that's based on science, right?
A. Yes. Because that's how the medication is cleared out of your system.
Q. Are all anticoagulant medications appropriate for all patients?
A. No.
Q. Pradaxa has been on the market now for almost eight years, right?
A. Yes.
Q. So have all of the anticoagulant patients switched to Pradaxa from warfarin?
A. No.
Q. Well, why is that? Why would patients still use warfarin if they had Pradaxa available?
A. Because of the problems we have been discussing. There are a certain patient population where Pradaxa or other anticoagulants are not suitable for them. They may have more side effects than they will have with coumadin. So it's not for everybody.
Q. You were asked about the Medication Guide. Do you remember that on cross?
A. Yes.
Q. I didn't ask you about it on your direct exam, but I want to ask you about it now since it was brought out in cross-examination.

You read the Medication Guide that Betty and her family received, right? You read it?

A. Yes.

Q. Did it tell them that Pradaxa hadn't been tested in patients like Betty?

A. No, it does not say that.

Q. Did it tell them that that dose had never been tested?

A. It does not.

Q. Did it tell them don't take Pradaxa if you take Coreg?

A. It does not.

Q. Did it tell them don't take Pradaxa if you take any P-gp inhibitor?

A. It does not.

Q. Did it tell them that there was no reversal agent for Pradaxa?

A. If does not.

Q. Did it tell them that Betty was more likely to have a GI bleed on Pradaxa than she was on warfarin that she had already been on?

A. I don't believe they told her that.

MR. CHILDERS: I don't have anything else, Your Honor.

MR. LEWIS: May we approach?

THE COURT: Yes.

(Bench conference, reported.)

MR. LEWIS: Maybe I opened the door, but he directly

violated the Court's ruling on the 75 and not tested and not in the Medication Guide. I didn't ask him about that on his cross-exam. I asked him specific things about the Medication Guide. I never touched that 75 or that renal function, never touched it. I think he violated the motion in limine.

MR. CHILDERS: He opened the door, Your Honor.

THE COURT: How is that?

MR. CHILDERS: I didn't talk about the Medication Guide at all. What he said was this is information that not only the doctors have, but also the patients have and went through specific items that are listed in there. And I think we have a right to say, but things are not listed in there when he does that on cross-exam.

MR. LEWIS: The reason he can't offer those opinions doesn't change just because I covered that with him. Because he did offer opinions about the Medication Guide and the physician label in his report. It was all about risk of bleed -- everything that I covered was about risk of bleed and increased risk of bleed. I never touched on 75, and I never touched renal function.

So I get to cross-examine him on the opinions he did offer, but what I'm not allowed to do is try to cross-examine him on the 75 or the renal function and then preclude it. I never touched that, Your Honor.

MR. CHILDERS: May I?

THE COURT: Yes.

MR. CHILDERS: He didn't offer opinions on the Medication Guide in his report or in his deposition. He opened the door on that. We had this discussion before.

THE COURT: He didn't open the door that you raised in the motion, so I do think that you violated the order. The question is now what is the remedy you'd like to suggest to the Court?

MR. LEWIS: Can we give that some thought? I mean, it's already out.

THE COURT: Are you finished with him?

MR. CHILDERS: Yes.

MR. LEWIS: I have very brief recross.

THE COURT: So --

MR. LEWIS: I don't want to touch it on recross.

THE COURT: One option would be that the Court can instruct the jury that to the extent what was commonly a failure of the label to test the 75 dose or testing of patients with severe renal problems, the expert is not offering an opinion that the label is deficient based on that. That's outside the scope of his opinions.

MR. LEWIS: And they can't consider it.

MR. CHILDERS: That's fine.

THE COURT: Okay.

MR. LEWIS: They can't consider it.

THE COURT: I don't want to say you can't -- yeah, they might get confused. You can't consider the fact even if established by some other expert's opinion?

The point is to say this witness wasn't offering an opinion that the label was deficient for failure to report in the label the 75 dose testing or the testing on patients with severe renal problems.

MR. LEWIS: Okay. The instruction works out. You need to put the flip chart away.

MR. CHILDERS: Sure.

THE COURT: All right. So do you want me to give this instruction first and then you're going to recross or after you recross?

MR. LEWIS: How about after recross?

THE COURT: Okay.

MR. CHILDERS: Thank you.

(Bench conference, concluded.)

THE COURT: All right. I think we're almost done with this witness. Are you folks okay for another five or ten minutes to do that?

Okay. Great. That will save us time in the long run, I believe.

All right. Recross.

MR. LEWIS: Yes, Your Honor, very briefly.

Thank you, Members of the Jury and Dr. Ashhab for

hanging in there today. I appreciate trying to get you finished up.

RECROSS-EXAMINATION

BY MR. LEWIS:

Q. The first thing I need to do is stand corrected. You pointed out a mistake that I made in a slide that I created last night before I examined you, and that was with respect to the aPTT levels. So I do want to cover the documents that you covered with Mr. Childers, though, because I clearly misread the medical records.

But I think I read something correctly, and I just want to make sure that I get it correct. Okay?

A. Okay.

MR. LEWIS: I'm going to go to 9009A.

Q. And these are corresponding to those dates that you covered with Mr. Childers on the PT levels.

A. Yes, sir.

Q. And the first one I want to cover is 179, 9009A-179.

A. Yes.

Q. Definitely there's a PT test. That's not aPTT, right?

A. Yes.

Q. A different test.

But there is an INR reading?

A. Yes.

Q. And the INR reading is elevated, correct?

A. Correct.
Q. Okay.
(Off the record.)
BY MR. LEWIS:
Q. That's elevated. That's a higher risk of bleed at that time?
A. Correct.
Q. Okay. If we go to 9009-206, that was another one mentioned on that slide.
A. Correct.
Q. There we do have an aPTT level at 62, right?
A. Yes.
Q. That's elevated, correct?
A. Yes.
Q. And if you go down to the INR, that is 4.3. That is elevated, correct?
A. Correct.
Q. Okay. If we go to -- the next one that I mentioned was in 383. There's that PT again. That is 75.7.
That's not aPTT, correct?
A. One more time the page, please?
Q. 383. Sorry. Thank you, Doctor.
A. Yes, sir.
Q. Okay. But the INR is elevated, and that is 6.3?
A. Correct.

Q. Higher risk of bleed?
A. Correct.
Q. The next one is 389.
There is no aPTT test there, correct?
A. Correct.
Q. But there is an INR test. That is at 8.0 on October 10, 2011.
A. Correct.
Q. That is significantly elevated, correct?
A. Correct.
Q. Okay. The next one is 9009-451. Again, not aPTT, my mistake. But there is an INR, and that is elevated again, correct?
A. Yes.
Q. Okay. And the last one is 461. Again, no aPTT, my bad. But the INR is measured, and that is elevated again, correct?
A. Correct.
Q. Okay. I apologize for the mistake that I made in the slide, but the records do reflect that on each of the occasions that we've just discussed, Mrs. Knight was at a higher risk of bleed because of her higher INR levels on warfarin, correct?
A. Correct.
Q. Okay. The last thing I want to discuss is the Pradaxa physician label. That is Exhibit 5889.

And first of all, if you look at the Warnings and Precautions, risk of bleeding is on the first page of the physician label, correct?

A. Correct.

Q. Any physician who is prescribing anticoagulant medication is going to understand there is a significant risk of bleeding when prescribing that medication, right, Doctor?

A. Correct.

Q. Does it matter whether it's on the left side or the right side on the first page of the physician label?

A. No, but there is a box where something kind of attracts your attention more. So you pay attention if you see it outlined or in bold. But whether it is on the right or the left, no.

Q. On page 5889-04, there is -- this is a physician label.

By the way, do you read physician labels?

A. I read them when it pertains to a certain patient's risk, yes.

Q. Right.

And do you sometimes read study results?

A. I do.

Q. Okay. And do you take those into account when you're prescribing medication for your patients?

A. That's correct.

Q. And you understand that some medications have higher risks

of one thing and lower risks of another?

A. Correct.

Q. And you, as a physician, have to take those -- the menu unfortunately of risks that come with a medication and factor that into your decision, right?

A. Correct.

Q. And then you also have to understand the benefits of a particular medication, right?

A. Correct.

Q. Okay. And you know that BI, Boehringer ran a clinical trial called the RE-LY study that is reflected in this label, right?

A. Yes.

Q. And that study did reflect, as indicated here, there was a higher rate -- right under the chart, the second paragraph -- there was a higher rate of major gastrointestinal bleeds in patients receiving Pradaxa.

That's the higher dose, the 150, right?

A. Yes.

Q. That is right in the physician label, right?

A. Yes.

Q. There are no secrets here.

Boehringer is telling physicians, in our trial, we did have a higher rate of major gastrointestinal bleeds, correct?

A. Yes.

Q. That's what they should be telling physicians if that is what the data shows, correct?
A. Correct.
Q. But you also know that in that same chart that is just above there, Pradaxa performed better in a different type of risk, correct?
A. Correct.
Q. Do you know what a brain bleed is?
A. Yes.
Q. And that's what is referred to when it's intracranial hemorrhage?
A. Yes.
Q. Okay. You see Pradaxa had a lower risk of that particular complication, right?
A. Yes.
Q. And brain bleeds or intracranial hemorrhages can be very, very serious complications, too, right?
A. Yes.
Q. So these physicians have to make this choice, well, I've got a lower risk of a brain bleed, but maybe a higher risk of a GI bleed.

Those are the choices that physicians have to make when they are assessing an individual patient, right?
A. Correct.
Q. And one physician may choose to avoid the brain bleed and

take the high risk of a gastrointestinal bleed, correct?

A. Depending on the clinical scenario, and each particular patient is unique.

Q. Right.

And if we look at 5889-08, you also know, don't you, that that RE-LY study, as this chart reflects, showed that Pradaxa had a lower risk of stroke events as compared to warfarin in that trial, right?

A. Yes.

Q. That's a benefit, right?

A. Yes.

Q. So when we look at the full menu of risks and benefits, we've got three things to consider at least, right? We've got to consider that in the trial Pradaxa offered better stroke protection, correct?

A. Yes.

Q. Better avoidance of risk of brain bleed, correct?

A. Yes.

Q. But at a higher risk of GI bleed, correct?

A. Correct.

Q. And so the physician has to balance those things, among others, when prescribing Pradaxa to a patient, correct?

A. In general.

Q. Okay. In general?

A. For Mrs. Knight, it was the wrong drug to start with.

Q. Understood.

But her physicians might have chosen -- we know this.

We know that she didn't have a stroke while she was on Pradaxa, correct?

A. Correct.

Q. We know that she didn't a brain breed while she was on Pradaxa, correct?

A. Correct.

Q. And those things could have been way more important to her physicians than the GI bleed risk, correct?

A. But that's not what the case turned out to be.

Q. Understood.

A. That's the problem. It's -- what you're talking about here is all correct for the general population, maybe for the majority of the population. The problem we face here with Mrs. Knight is she's in that minority of population who has multiple medical problems, kidneys are not working properly, taking medications that interfere with the medicine. So she is, in my opinion, the wrong patient to take that medication.

I'm not saying the medication is a bad medication. It's a very good medication, but I think it was given to the wrong person. I think there ought to be something to tell the physician don't give this drug to this patient.

It is probably good for the next person, the next ten people after Mrs. Knight. But for her, I think it was the

wrong medicine, and I think the doctors were not fully informed that they shouldn't have given her the medicine. That's all what I'm trying to say.

Q. Doctor, yes or no, Mrs. Knight's physicians could have chosen to take the risk of the GI bleed to get the benefits of better stroke protection and the avoidance of a brain bleed.

That's a choice that her physicians might have made, correct? Yes or no?

A. The issue is I don't know if they were fully informed about these risks.

I mean, we're not really comparing apples with apples here because the risk of stroke in atrial fibrillation is less than 5 percent anyway. But the risk of bleeding may be a lot more in somebody with poor creatinine clearance who takes Coreg. So it's not comparing apples with apples and saying it's a bleed in the brain or in the colon. No, the likelihood of having that event is very different.

So you're trying to prevent a stroke. Well, what are the chances of getting a stroke in an AFib patient? It's 2 to 3 percent, less than 5 percent anyway.

Q. Can you answer my question, Doctor?

A. Yes, sir.

Q. Okay. I'll give it another run.

Mrs. Knight's physicians, when choosing to put her on Pradaxa in April of 2013 and combine it with Plavix and

aspirin, could have been choosing to avoid the risk of brain bleed, get the benefit of stroke protection and take on the risk of gastrointestinal bleeding? That's the choice that they could have made at that time, correct?

A. They could have.

Q. Okay. And isn't it true that you, in your practice, Doctor, don't make those type of risk-benefit decisions for anticoagulant medication.

You don't prescribe anticoagulant medication, do you?

A. But I do participate in these decisions. When somebody has GI bleeding, then I'm part of the team. It's a consultation between the cardiologist, the primary care physician and the gastroenterologist to reach what you just talked about, what is the best medicine for that person.

Q. That's not my question.

You don't prescribe anticoagulant medication, and so you don't make the ultimate risk and benefit determination for those patients, correct?

A. Partially correct. I do not prescribe the medication, you are correct.

Q. Thank you, Doctor.

A. I do contribute to the decision to prescribe.

MR. LEWIS: Thank you for your time.

THE WITNESS: Thank you.

THE COURT: All right. Any --

MR. CHILDERS: Judge, can we see you one more time?

THE COURT: Yes.

(Bench conference, reported.)

THE COURT: So make sure you use the microphone.

MR. CHILDERS: To address this issue with the testing, he just went through the RE-LY study results with him that don't include the 75 milligram or severe renal patients. Right after we just had this discussion, and we agreed we were going to give a limiting instruction, he went into trying to convince the doctor to tell the jury that a patient is better off on Pradaxa than warfarin when it hasn't been tested at that dose.

MR. LEWIS: No, he testified on redirect about the gastrointestinal bleed increase. He covered the very same line that I just addressed with him, and my only rebuttal to that was there's more than one risk to consider. I never talked about the dosage.

THE COURT: Okay. I agree with the defendant.

MR. CHILDERS: Fair enough, Your Honor. Thank you.

MR. LEWIS: Thank you.

(Bench conference, concluded.)

THE COURT: All right. Doctor, that concludes your testimony. Thank you. You may step down.

THE WITNESS: Thank you.

THE COURT: All right. Ladies and Gentlemen, there's

one matter I need to instruct you concerning.

At the close of the redirect examination by Mr. Childers, if you recall, he used the handwritten chart that he had developed in his opening statement, and he walked through that chart with Dr. Ashhab, asking him about opinions with respect to the adequacy, the sufficiency of the label as to each of those points.

An expert in a case is required to disclose opinions in advance of trial, and the Court has determined here that two of the opinions that he offered in that brief questioning were not opinions that he had offered during the course of his disclosures of his expert opinions. So I want to give you an instruction concerning those.

Specifically on that chart, it was noted in response to plaintiffs' counsel's questions that there was, first, what he considered a failure to include as a warning in the label the fact that Pradaxa was not tested on people with severe renal impairments. Secondly, he also testified an opinion that the label was inadequate because the testing was not done on people taking -- in studies, on people taking 75-milligram doses.

The Court would find and instruct that those were two opinions that were outside of his disclosure. To the extent plaintiff is relying upon those as evidence of a defect, they have to get that evidence from other witnesses besides Dr.

Ashhab. Dr. Ashhab is not permitted to testify to those two specific opinions because he didn't disclose them before. If the plaintiff make arguments about those alleged failures of the label, they have to depend upon someone other than Dr. Ashhab for that testimony.

Do counsel have any quarrel with the instruction that I've given?

MR. CHILDERS: No, Your Honor.

MR. LEWIS: No, Your Honor.

THE COURT: All right. With that, Ladies and Gentlemen, that concludes our work for today. I'm going to excuse you until 9:00 a.m. tomorrow.

Remember, as we have done throughout the trial, I'm ordering that you not discuss the case with anyone or try to do any investigation or look into any matters on your own. With that, I'll see you back here at 9:00 a.m. tomorrow.

I do have one brief housekeeping measure to take up with counsel. If you can stick around, it will only take a minute. The jury is excused.

(Jury not present.)

THE COURT: As the jury leaves, I want to clarify with counsel a couple of the exhibits.

Mr. Lewis, you used in your examination an exhibit that is the -- I don't remember if it has a number, but it's a colored chart that shows the INR values up and down. You said

that you were offering that chart into evidence under Rule 1006. And then either in the exchange or in response to Mr. Childers' objection, you said that you have an exhibit which I've seen that purports to be a summary of all of the medical records that include or are included in the INR reporting history, and that has been marked as Exhibit 9009S.

MR. LEWIS: Yes.

THE COURT: And so as I understand the rule, I think if counsel for the plaintiffs has no objection to the accuracy of the 9009S chart, that it's admissible under 1006 as a chart or summary based upon voluminous documents that can be admitted into evidence to establish the contents of the document.

And as I understood it, these are documents, medical records that have been obtained through the certification process and, as I understood it, disclosed to plaintiffs beforehand. If that's not the case, then we need to address that.

But it seems to me that this chart and the accompanying medical records may be admitted as one exhibit. But I considered the first chart that you had to be a demonstrative aid, which is not admitted into evidence.

MR. LEWIS: Correct.

THE COURT: So is that the way you offer and intend to use these two different documents?

MR. LEWIS: Yes. The color chart is a demonstrative only. The more generic chart with the numbers in it was the summary --

THE COURT: Okay.

MR. LEWIS: -- for admission.

THE COURT: Right. Okay.

MR. CHILDERS: Thank you, Your Honor.

The only thing I would ask is we did get that, but it was today. I'm certain it's probably right. If you would just give us overnight to look at it --

THE COURT: I'll withhold ruling on the admissibility of 9009S until plaintiffs have had a chance to review the underlying records.

MR. CHILDERS: Thank you, Your Honor.

THE COURT: In any event, the first chart you used is a demonstrative aid only.

MR. LEWIS: Correct.

THE COURT: All right. Thanks for clearing it up.

Is there anything else we need to take up today?

MR. CHILDERS: We have many exhibits that came in today, and we talked to Terry about doing those first thing in the morning because it's a little late.

Is that --

THE COURT: Sure. That's fine.

MR. CHILDERS: Thank you, Your Honor.

MR. LEWIS: Thank you.

THE COURT: See you back here at 9:00 a.m. tomorrow.

Let's try to start about five minutes early, if you don't mind. If we've got all of the jurors back here, we can do the exhibits then.

MR. CHILDERS: Yes.

THE COURT: Thank you.

THE COURT SECURITY OFFICER: All rise. This honorable court will be adjourned.

(Proceedings were adjourned at 5:34 p.m.)

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CERTIFICATION:

We, Kathy L. Swinhart, CSR, and Lisa A. Cook, RPR-RMR-CRR-FCRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on October 9, 2018.

October 10, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR

/s/ Lisa A. Cook
LISA A. COOK, RPR-RMR-CRR-FCRR